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The Japan Electrical Manufacturers' Association(JEMA)

17-4, Ichiban-cho, Chiyoda-ku, Tokyo 102-0082
TEL 03-3556-5886

原5702

# Quality Assurance Activities

for Nuclear Power Plants in Japan **2023**

The Japan Electrical Manufacturers' Association

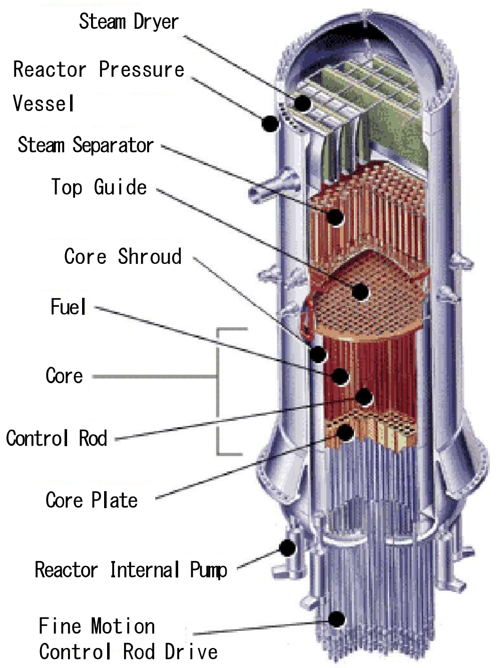
Plant conceptual design

Piping layout drawing

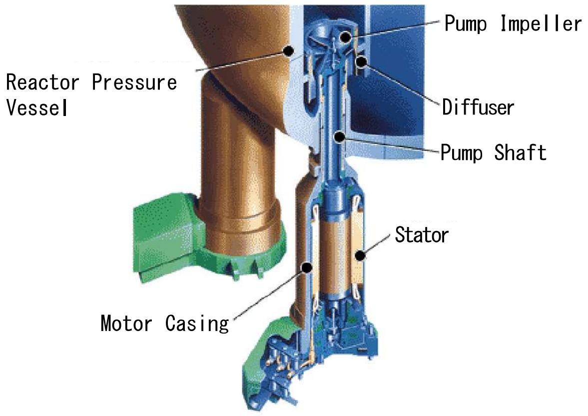

On-site scanning
with laser scanner

Three-dimensional data
created by on-site scan data

Basic planning and design of plant based on three-dimensional CAD

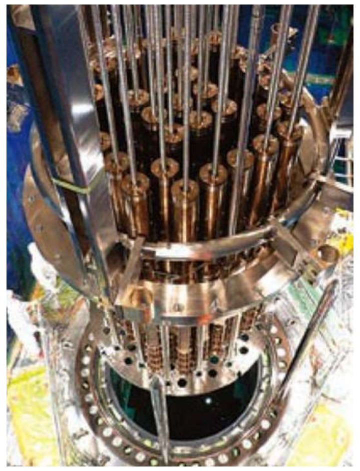



Cut model of reactor internals




Cut model of reactor internal pump

Installation of
reacter vessel



Installation of
Core internal

Construction of nuclear power plant

# Quality Assurance Activities for Nuclear Power Plants in Japan 2023

Issued in December,2024

Published by The Japan Electrical Manufacturers' Association(JEMA)

17-4, Ichiban-cho, Chiyoda-ku, Tokyo 102-0082
Phone： 03-3556-5886 (Nuclear Energy Systems Department)
FAX ： 03-3556-5890 (Nuclear Energy Systems Department)
URL ： https://www.jema-net.or.jp/

The Quality Assurance Committee for Nuclear Power Plants
Toshiba Energy Systems & Solutions Corporation
Hitachi-GE Nuclear Energy, Ltd.
Fuji Electric Co., Ltd.
Mitsubishi Heavy Industries, Ltd.

# Preface

The Quality Assurance Committee for Nuclear Power Plants of the Japan Electrical Manufacturers' Association (JEMA) identifies issues on the quality assurance of nuclear power plants, examines and discusses efforts to improve the reliability of nuclear power generation from the standpoint of manufacturers, and conducts activities such as providing recommendations and coordination for not only JEMA members but also related organizations and groups.

This booklet, “Quality Assurance Activities for Nuclear Power Plants”, was prepared with the aim of promoting understanding of nuclear power plants among JEMA members and serves as a reference material for companies planning to get involved in nuclear-related businesses and for companies that are interested in nuclear quality assurance.

The first edition of this booklet was issued in 1994, followed by three revised editions in 2001, 2006, and 2011. We are pleased to announce that we have just issued the fourth revised edition to reflect the new regulatory standards incorporating the lessons learned from the accident at the Fukushima Daiichi Nuclear Power Station and the private nuclear industry's self-controlled efforts to improve safety and other initiatives.

# Contents

# Ⅰ. Present status of Nuclear Power Plants

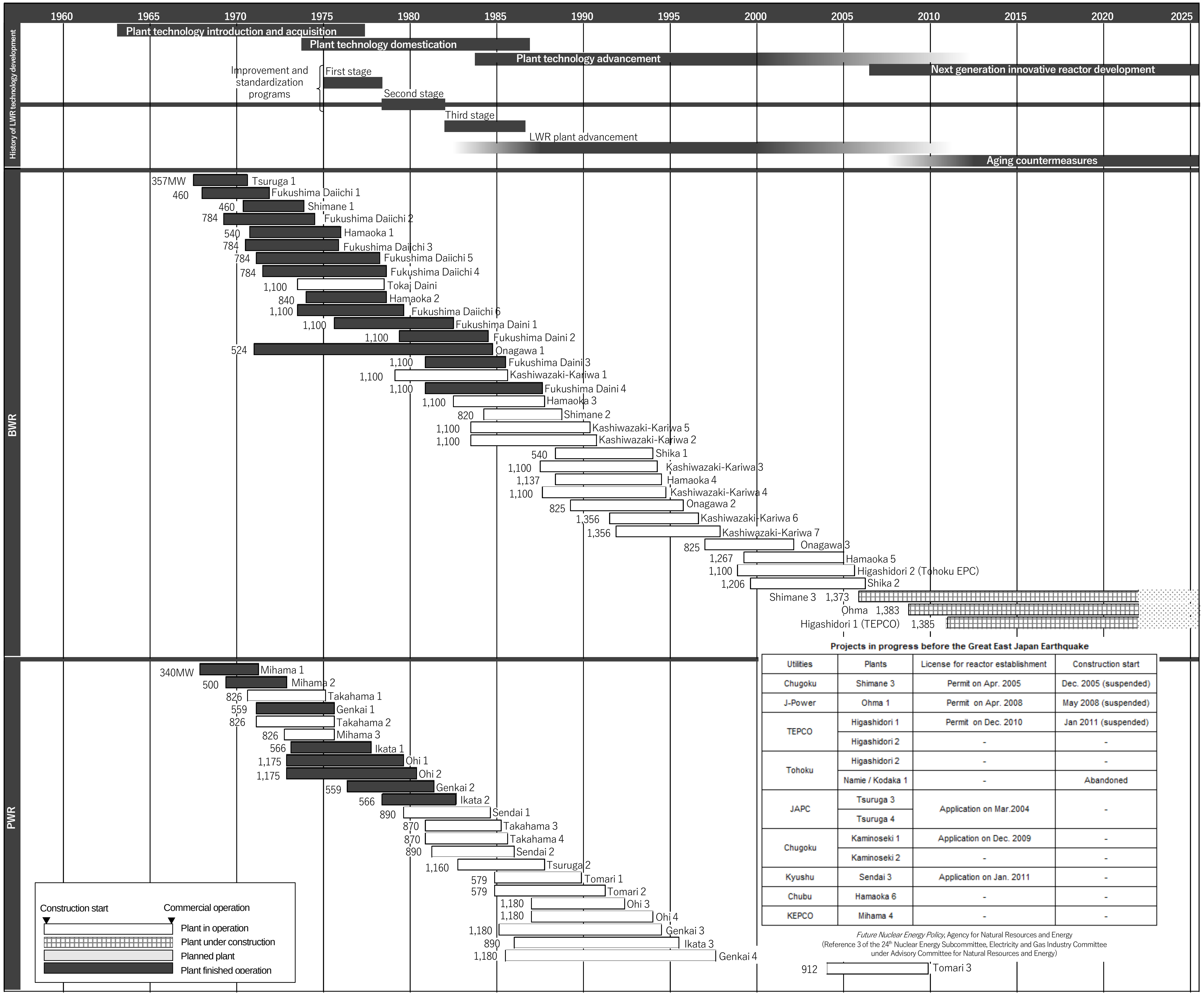
## 1. Trends in Construction of Nuclear Power Plants in Japan

Nuclear power plants in Japan were light water reactors (LWRs). The technology for these reactors was first introduced from the United States to Japan to acquire practical skills, and then the introduced technology was digested and domesticated. Meanwhile, the public and private sectors jointly improved and standardized the LWRs based on their construction and operating experience, with the aim of enhancing plant safety and reliability through domestic technology, increasing plant availability factors, and reducing occupational radiation exposure. Since then, plant safety and reliability have been further improved on the basis of enhanced technology, and high capacity factors and low unscheduled shutdown rates in nuclear power plants have been pursued through the improvement of operating and maintenance technology.

During and after the 2000s, nuclear power generation has been more appreciated as it meets the world's increasing energy demands with the economic growth in the newly developed countries and reduces carbon dioxide emissions deemed to cause global warming. That accelerated new plant construction plans, but after the accident at the Fukushima Daiichi Nuclear Power Station triggered by the Great East Japan Earthquake in 2011, only twelve existing nuclear power plants passed the new regulatory requirements to restart as of September 2023, and the new plant construction/ modification/ replacement projects have been stagnant.

According to the Sixth Strategic Energy Plan approved by the Cabinet in October 2021, the Government of Japan has been implementing the policy for utilizing renewable energy and other resources as a core power source.　In that implementation, some issues are recognized, such as a surge in demands, system instability, and how to respond to the changes in international situations regarding energy resources.

In the Basic Policy for the Realization of GX (Green Transformation) approved by the Cabinet in February 2023, the Government of Japan is committed to contributing to the realization of carbon neutrality and utilizing nuclear power "through the development and construction of next-generation advanced reactors with built-in new safety mechanisms" for stable energy supply and economic growth.




**Projects in progress before the Great East Japan Earthquake**

| Utilities | Plants | License for reactor establishment | Construction start |
|---|---|---|---|
| Chugoku | Shimane 3 | Permit on Apr. 2005 | Dec. 2005 (suspended) |
| J-Power | Ohma 1 | Permit on Apr. 2008 | May 2008 (suspended) |
| TEPCO | Higashidori 1 | Permit on Dec. 2010 | Jan 2011 (suspended) |
| | Higashidori 2 | - | - |
| Tohoku | Higashidori 2 | - | - |
| | Namie / Kodaka 1 | - | Abandoned |
| JAPC | Tsuruga 3 | Application on Mar.2004 | - |
| | Tsuruga 4 | | |
| Chugoku | Kaminoseki 1 | Application on Dec. 2009 | - |
| | Kaminoseki 2 | - | - |
| Kyushu | Sendai 3 | Application on Jan. 2011 | - |
| Chubu | Hamaoka 6 | - | - |
| KEPCO | Mihama 4 | - | - |

*Future Nuclear Energy Policy*, Agency for Natural Resources and Energy (Reference 3 of the 24th Nuclear Energy Subcommittee, Electricity and Gas Industry Committee under Advisory Committee for Natural Resources and Energy)

Fig. I-1-1: Track record of nuclear power plant construction in Japan (As of August 2023)

## 2. Present Status of Power Generation Facilities

The nuclear power plants are located throughout the country, from Hokkaido to Kyushu. Figure I-2-1 shows the details of their operations and construction status.

As of September 2023, among all nuclear power plants in Japan, twelve reactors are operating, five reactors have Permission for the Installation /Modification, ten reactors are under review and inspection for compliance with the new regulatory requirements, and nine reactors are before submitting applications for review and inspection for compliance with the new regulatory requirements.

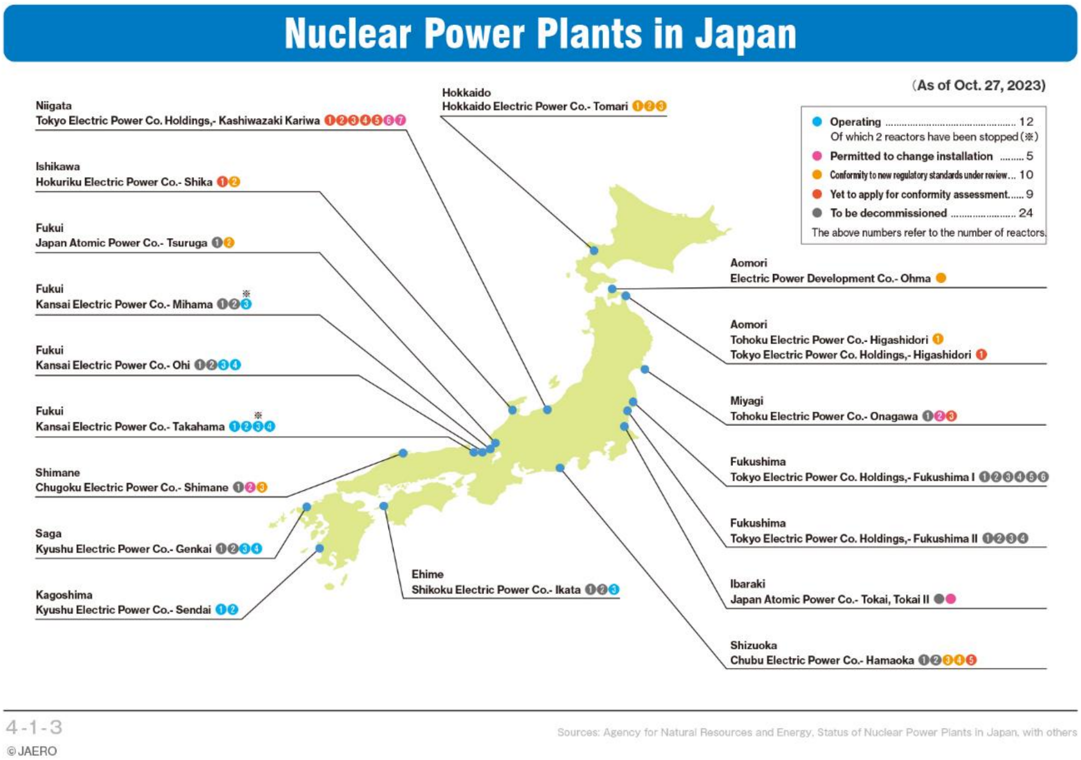



Fig. I-2-1: Status of operation and constructions of nuclear power stations in Japan

JAERO, Graphical flip-chart of Nuclear and Energy Related Topics

## 3. Plant Capacity Factors and Operating Performance

The capacity factor of the nuclear power plants in Japan had been constantly maintained at a level of 70% to 80% after it exceeded 80% in FY 1995. However, this figure dropped to 50% to 60% in FY 2003 and 2004, affected by some deceptive records of self-controlled inspection released in August 2002. The plant capacity factor in FY 2007 and 2008 dropped to approximately 60% due to such factors as the shutdown of a power station resulting from the Niigataken Chuetsu-oki Earthquake, increased outage periods for periodic inspection and other problems. Further, all nuclear power plants in Japan were shut down for periodic inspections in sequence after the accident at the Fukushima Daiichi Nuclear Power Station in the wake of the Great East Japan Earthquake in 2011. Then, the utilities applied for Permission for the Installation/ Modification and others according to the new regulatory requirements and restarted the plants that passed the NRA reviews and inspections.

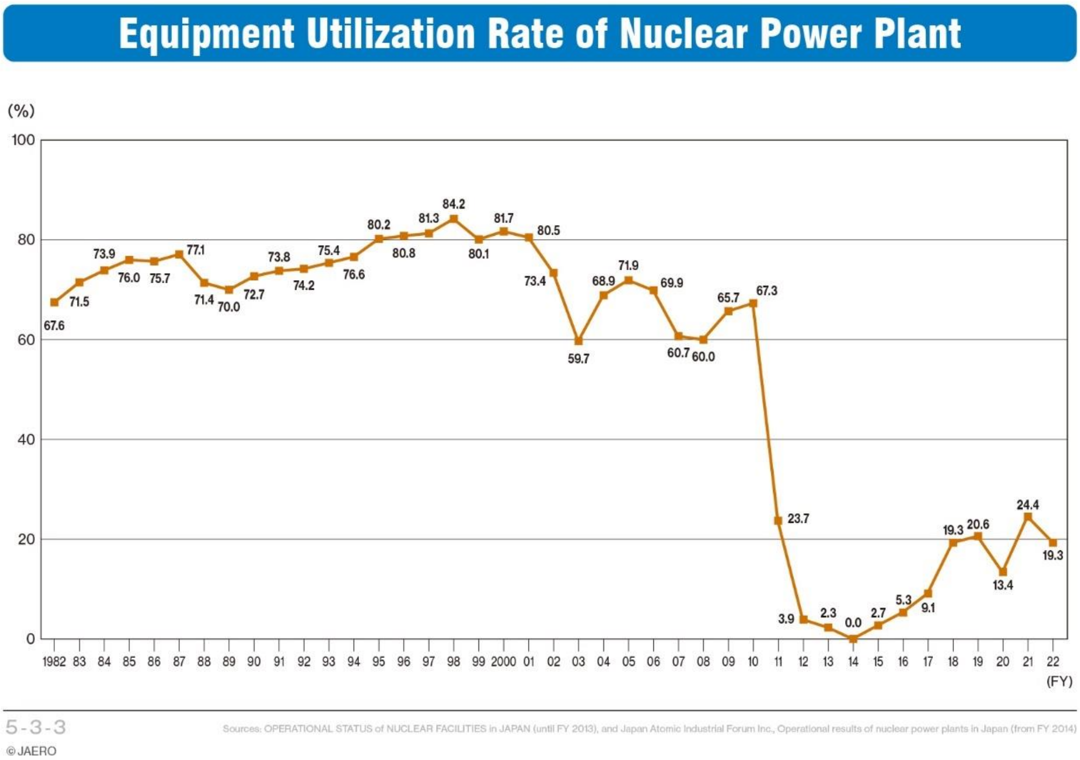



Fig. I-3-1: Equipment Utilization Rate of Nuclear Power Plant

JAERO, Graphical flip-chart of Nuclear and Energy Related Topics

## 4. Code and Regulatory Systems for Constructing Nuclear Power Plants

The new regulatory requirements were established for the nuclear power utilities to build nuclear power plants by the law amendment (*1) based on the lessons learned from the accident at the Fukushima Daiichi Nuclear Power Station in March 2011. Since April 2020, the new inspection system for nuclear facilities, the nuclear regulatory inspection by the NRA (hereinafter referred to as "NRA Inspection"), has started operation, which renewed the regulator's former pre-operational and other inspections. Licensees must implement self-controlled inspection as their primary responsibility. Then, the Nuclear Regulation Authority (NRA), a national administrative agency of the Cabinet of Japan, comprehensively reviews and evaluates how the licensees perform the overall activities for safety, including the results of the self-controlled inspection. Figure I-4-1 shows this new regulation.

A nuclear power utility (an applicant) planning to construct a nuclear power plant must submit to the NRA an application for Permission for the Installation describing the fundamental design concept and other information and then undergo safety reviews to get the license. After being granted the license, the nuclear power utility (the licensee) needs NRA approval of the design and construction plan (hereinafter referred to as "Approval of Design and Construction Plan") (*2). The licensee must also obtain approval from the NRA for Safety Regulations Programs (*3) to start construction.

After the Approval of Design and Construction Plan, the licensee must conduct inspections during each phase of construction to ensure that the facility is as approved for the Licensee's Pre-Operational Inspection (*4). The inspection results must be reviewed by the NRA Inspections (*5). The NRA Inspections include reviewing the quality management system (QMS) that the licensee implements. NRA inspectors may perform on-site inspections at the licensee and relevant parties, including its suppliers' manufacturing and other facilities. Before starting the operation, the NRA Inspection implements overall reviews of the licensee's safety activities for adequacy, including these inspections (*6).

As described above, the licensee begins operation on a commercial basis following the licensee's inspections to confirm conformity with the technical criteria and the Approved Design and Construction Plan, as well as undergoing the NRA Inspections. After starting the operation, the licensee must perform self-controlled periodic inspections (hereinafter referred to as "Periodic Licensee's Inspection" ) to confirm that conformity with the technical criteria for its safety functions is maintained. The NRA reviews and evaluates the results of the Periodic Licensee's Inspection and the licensee's safety activities in light of the plant-specific safety-evaluation criteria through the

NRA Inspections (free access and team inspections). If the NRA identifies deterioration, questions, or other findings in nuclear safety during the NRA Inspection, it may limit the plant operation or conduct additional inspections until the correction is verified.

(Notes and explanation)

*1: Reviews, licensing, and other regulatory inspections were conducted on the basis of two laws, the Act on the Regulation of Nuclear Source Material, Nuclear Fuel Material and Reactors (hereinafter referred to as the Reactor Regulation Law) and the Electricity Business Act. With their amendment in 2012, some of the latter were moved into the former. At the same time, the responsibility for the regulator's reviews and inspections was shifted from the Nuclear and Industrial Safety Agency in the Ministry of Economy, Trade and Industry (METI) to the NRA.

*2: With the law amendment above, Approval of the Construction Plan (Construction Approval) changed to Approval of Design and Construction Plan. In addition, the quality management program (the licensee's QMS) becomes a new subject to review in the approval above.

*3: The law amendment above revised the licensee's operation management using the Safety Regulations Programs subject to approval before starting the operation to subject to approval before starting construction, including construction and facility management.

*4: From April 2020, the Regulator's Pre-Operational Inspection changed to the Licensee's Pre-Operational Inspection. The operator's welding inspection was replaced with the Licensee's Pre-Operational Inspection on Welding. The NRA reviews the results of these inspections during the NRA Inspections.

*5: NRA Inspections are legal checks conducted based on an application for the Approved Design and Construction Plan.

*6: The NRA will notify the licensee of a rating resulting from the NRA Inspections.

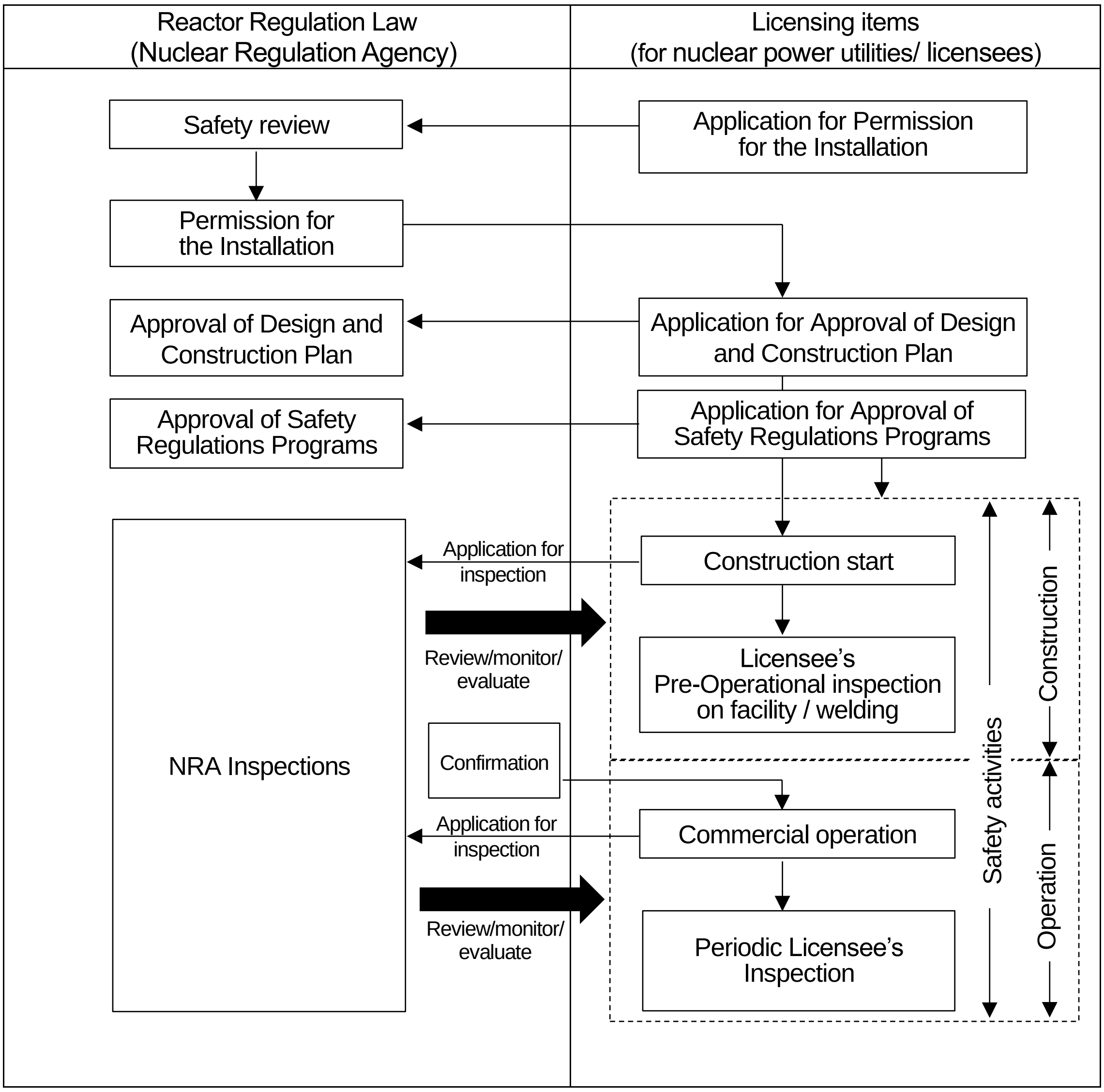



Fig. I-4-1: Code and regulatory systems for the construction of nuclear power plants

## 5. Flows of Activities for Enhancing the Safety and Reliability

The regulator sufficiently reviews the nuclear power plant's construction, modification, and operability to ensure its safety and reliability under the new regulatory standards that tighten the former regulatory standards based on the reflection from the accident at the Fukushima Daiichi Nuclear Power Station and inputs from Japan and overseas.

At the subsequent design stage, the nuclear power utilities and plant manufacturers (including the manufacturers of pumps, valves, instruments, etc.) will jointly verify their facilities and systems to obtain a license from the regulator. In this process, they apply various reliability analysis techniques, such as the failure mode and effect analysis (FMEA) and fault tree analysis (FTA), for supporting the quality assurance of nuclear power plants.

At the subsequent stages of manufacturing, installation, and pre-operation, the quality checks by the nuclear power utility (including the Licensee's Pre-Operational Inspection) and the NRA Inspections are performed according to the level of importance of equipment or facilities. The public and private sectors work respectively to ensure safety and reliability.

Once plant construction is complete and operation is to begin, the nuclear power utility's operating experiences are fed back to the plant manufacturer. When failure or a problem occurs, the causes of any troubled items are clarified and measures to prevent recurrence are taken. This information, in addition to corrective action, is spread and reflected in the Periodic Licensee's Inspection and serves to maintain and improve equipment and facilities and achieve higher plant reliability.

The implementation of these quality-related activities of the nuclear power utility is ensured by the NRA, a national administrative agency of the Cabinet of Japan, which conducts the NRA Inspections to maintain neutrality and fairness. This aims to further enhance safety and reliability.

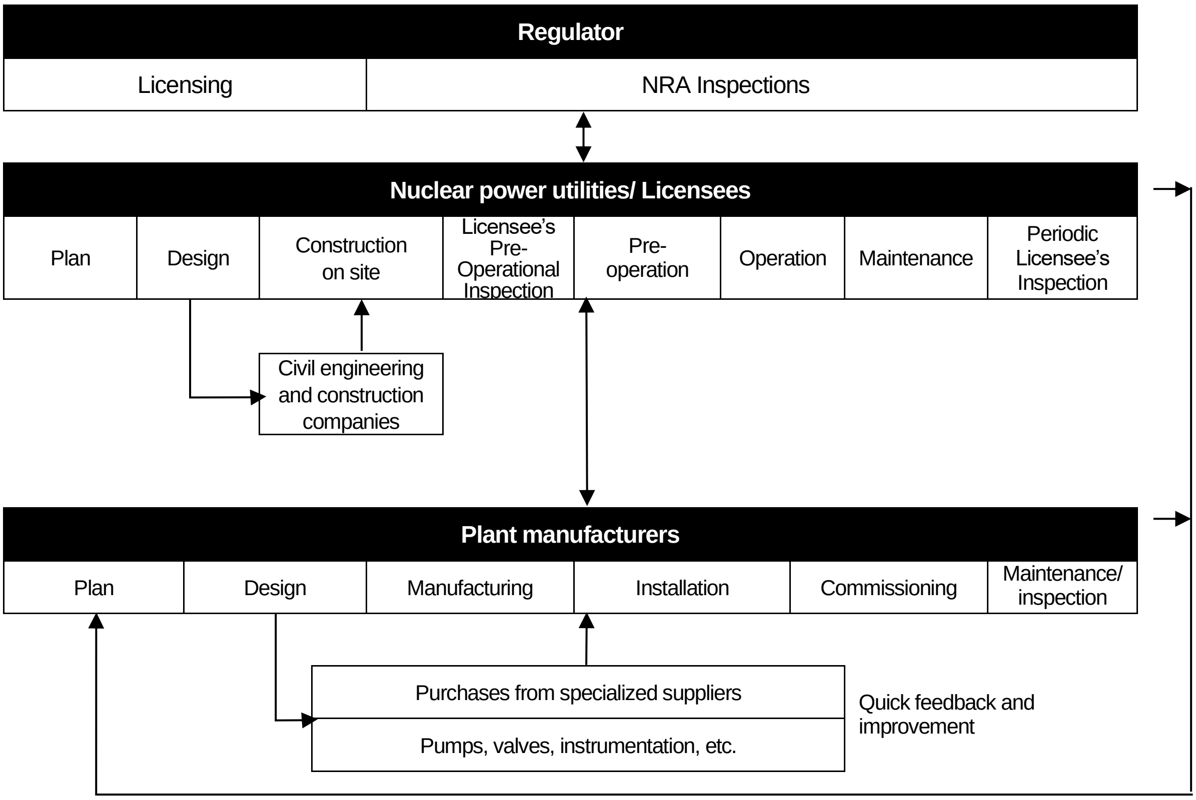



Fig. I-5-1: Flows of Activities for Enhancing the Reliability

## 6. Present Status of Nuclear Fuel Cycle Facilities

In Japan, a country with scarce energy resources, a nuclear fuel cycle that reuses plutonium and uranium in spent fuel is extremely important for raising the utilization rate of nuclear power generation resources to the maximum.

The process of manufacturing fuel assemblies to make fuel for nuclear power plants through conversion, enrichment, and reconversion from uranium ore, as well as a series of processes of reprocessing spent fuel and reusing the retrieved plutonium and uranium for nuclear fuel, are referred to as the "nuclear fuel cycle." To establish this cycle is essential for the effective use and stable supply of nuclear fuel. Figure I-6-1 shows the outline of the nuclear fuel cycle.

In Japan, the commercial spent-fuel reprocessing plant is under construction, aiming at early materialization of the nuclear fuel cycle. Figure I-6-2 shows the outline of nuclear fuel cycle facilities.

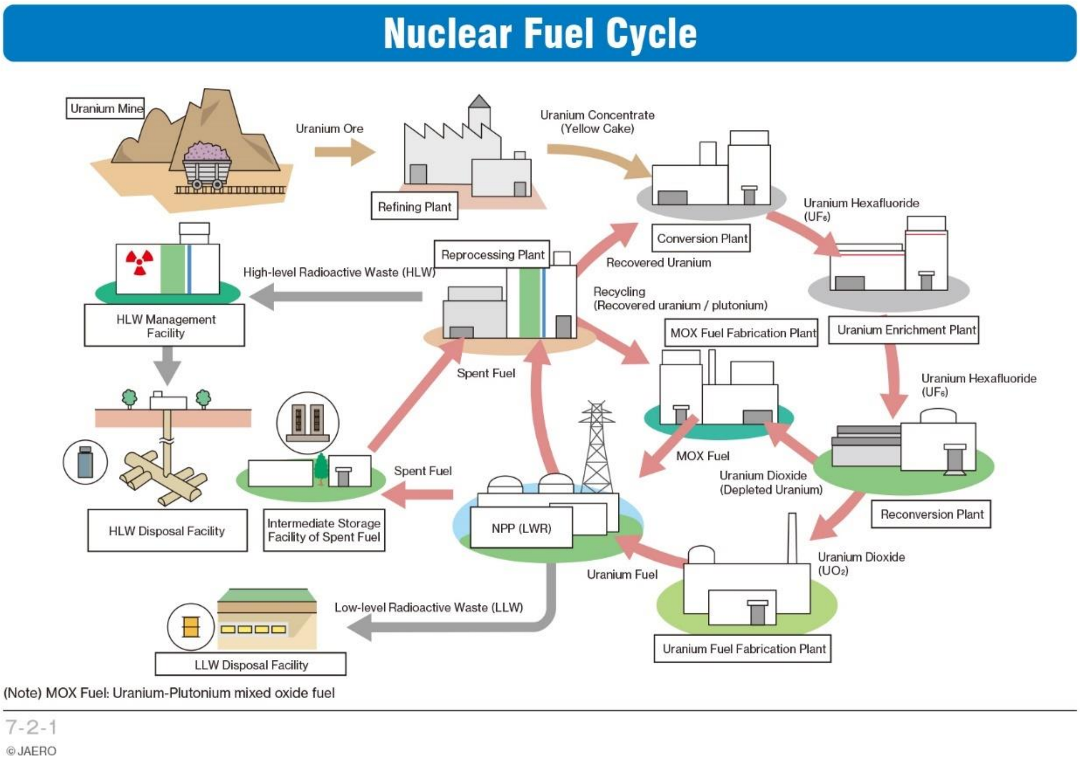



Fig. I-6-1: Nuclear Fuel Cycle

JAERO, Graphical flip-chart of Nuclear and Energy Related Topics

## Outline of JNFL's Nuclear Fuel Cycle Facilities

(As of the end of Dec. 2023)

| | Reprocessing Plant | Vitrified Waste Storage Center | MOX Fuel Fabrication Plant | Uranium Enrichment Plant | Low-level Radioactive Waste Disposal Center |
|---|---|---|---|---|---|
| **Location** | Aza-Okizuke, Oaza-Obuchi, Rokkasho-mura, Kamikita-gun, Aomori Prefecture | | | Aza-Nozuki, Oaza-Obuchi, Rokkasho-mura, Kamikita-gun, Aomori Prefecture | |
| **Capacity** | Area of site: approx. 3.9 million $m^2$ | | Maximum capacity: 130 t-HM$^{*2}$/y<br>MOX fuel assemblies for domestic light water reactors (BWR and PWR) | Area of site: approx. 3.4 million $m^2$ | |
| | Maximum yearly reprocessing capacity: 800 t-U$^{*1}$/year<br>Maximum daily reprocessing capacity: 4.8 tU$^{*1}$<br>Storage capacity for spent fuel: 3,000 t-U$^{*1}$ | Storage capacity for waste returned from oversea plants: 2,880 canistiers of vitrified waste | | 450 t-SWU$^{*3}$/year | [ Existing Facilities ]<br>Number one disposal facility: approx. 40,960 $m^3$ (Equivalent to 204,800 200-liter drums)<br>Number two disposal facility: approx. 41,472 $m^3$ (Equivalent to 207,360 200-liter drums)<br>[ Planned New Facilities ]<br>Number three disposal facility: approx. 42,240 $m^3$ (Equivalent to 211,200 200-liter drums)<br>Planned to be expanded to 600,000 $m^3$ |
| **Current Status** | Under construction | Cumulative number of stored canisters: 1,830 | Under construction | Operation stopped | Number one disposal facility: 151,803 drums<br>Number two disposal facility: 198,824 drums |
| **Schedule** | Start of construction: 1993<br>Completion: First half of 2024 | Start of construction: 1992<br>Business operation: 1995 | Start of construction: 2010<br>Completion: First half of 2024 | Start of construction: 1988<br>Business operation: 1992 | Start of construction: 1990<br>Start of disposal: 1992 |

＊1 U: The mass of uranium in the metal state.
＊2 HM: The mass of the metal component of plutonium and uranium in MOX fuel.
＊3 SWU: Separating work units when the natural uranium is separated from enriched uranium.

7-2-5



Source: Japan Nuclear Fuel Ltd., with others

Fig. I-6-2: Outline of JNFL's Nuclear Fuel Cycle Facilities

JAERO, Graphical flip-chart of Nuclear and Energy Related Topics

## 7. Future Activities for Nuclear Power

According to the Atomic Energy Basic Act, "The purpose of this act is to pursue the research, development, and use of nuclear power to secure energy resources for the future and facilitate academic and industrial advancement as well as prevention of global warming, for contribution to the welfare of human society and improvement of the national living standard." Following this principle, individuals engaged in the nuclear industry must continue promoting safe and secure nuclear energy development and use. In addition, with the lessons learned from the accident at the Fukushima Daiichi Nuclear Power Station in 2011, the nuclear industry must continue its collective and tireless efforts to comply with the safety standards of excellence and enhance further safety. It keeps such efforts to improve safety and quality with nuclear power utilities and ATENA/ JANSI/ NRRC (Note).

Recently, people have been expecting great things from nuclear energy to attain economic growth in the environmental energy areas, such as countermeasures against global warming (carbon neutrality), energy security measures, and green transformation (GX). Accordingly, the nuclear power plant manufacturers need to address these issues from their viewpoints while understanding their positions.

While responding to the needs of the times and aiming at having nuclear installations widely accepted by society, it is necessary to address technological issues such as “sophistication,” “life extension,” “availability improvement,” “extended-cycle operation,” “power uprating,” and “decommissioning” of nuclear power plants from the standpoint of manufacturers, and to establish and extensively conduct quality assurance activities in order to ensure and maintain safety and reliability at a high level in all stages from siting to decommissioning of nuclear installations.

One of the objectives of quality assurance activities at nuclear power plant manufacturers is, in short, to “satisfy applicable statutes, standards, codes, and customer requirements for quality, and achieve, maintain and improve nuclear safety, which is the overriding objective, by providing highly safe and reliable products and services to customers.” To achieve this objective at a high level in an enormous system like a nuclear power plant, it is necessary to establish and strengthen a quality management system that allows a prompt and flexible response to changes in society, and to continuously improve the effectiveness of the quality management system through consistent quality assurance activities with social responsibility in mind.

To achieve, maintain, and improve nuclear safety in terms of “attaching importance to compliance” and “fostering safety culture,” which will serve as the foundation for achieving the above objective, the nuclear power plant manufacturers need to remain trusted by society by thoroughly complying with the statutes, standards, and codes in good faith, fostering a culture that gives the highest priority to nuclear safety while recognizing social responsibility, and fulfilling social accountability.

In addition to ensuring and maintaining nuclear safety by raising awareness of safety and compliance, improving ethics and sharing safety culture among those involved in the nuclear industry, we will continue to work on the disclosure of information, public acceptance (PA) activities, etc., for winning trust in and understanding of nuclear energy from local residents and the public.

(Note) ATENA: Atomic Energy Association
JANSI: Japan Nuclear Safety Institute
NRRC: Nuclear Risk Research Center

# Ⅱ. Quality Assurance of Nuclear Power Plants

## 1. Characteristics of Quality Assurance of Nuclear Power

The “quality assurance” in the ISO 9000 series is “part of quality management focused on providing confidence that quality requirements will be fulfilled.” It is said that “demonstration” is required to provide confidence. Put simply, this term means “providing confidence in the ability to provide something promised through demonstration with evidence.”

The nuclear industry is strongly required to achieve “nuclear safety” because of its own characteristics.

Nuclear safety means “the achievement of proper operating and maintenance conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation hazards.” To achieve nuclear safety, it is necessary to give top priority to considering nuclear safety appropriately according to the importance of each duty when making individual decisions, and the attitude and status of an organization or individual who makes such individual decisions (concept of “safety culture”) are important.

“Safety” means that operating and maintaining a nuclear installation, in a technical sense, will pose no possibility of accident such as radioactive leakage. “Safety” of a nuclear installation should be achieved through the integrity of the installation's facilities and the ensuring of “safety culture” by humans who operate, maintain, and manage the installation. Furthermore, a “sense of safety” is provided to community people through the build-up of “safety” efforts and disclosure of information by nuclear power utilities and regulatory agencies.

On the other hand, after the accident at the Fukushima Daiichi Nuclear Power Station triggered by the Great East Japan Earthquake in 2011, a new regulatory agency, the Nuclear Regulation Authority, started up, and new regulatory standards took effect. In addition, the NRA imposes quality assurance requirements on nuclear power utilities as a national regulation under the Regulation on Quality Management System for Safety of Nuclear Facilities (hereinafter referred to as "QMS Regulation").

In addition to compliance with regulatory requirements, nuclear power utilities aim to achieve "nuclear safety" by building their quality management systems suitable for their organizational context, utilizing a private-sector standard, the Management System Code for Nuclear Safety: JEAC 4111.

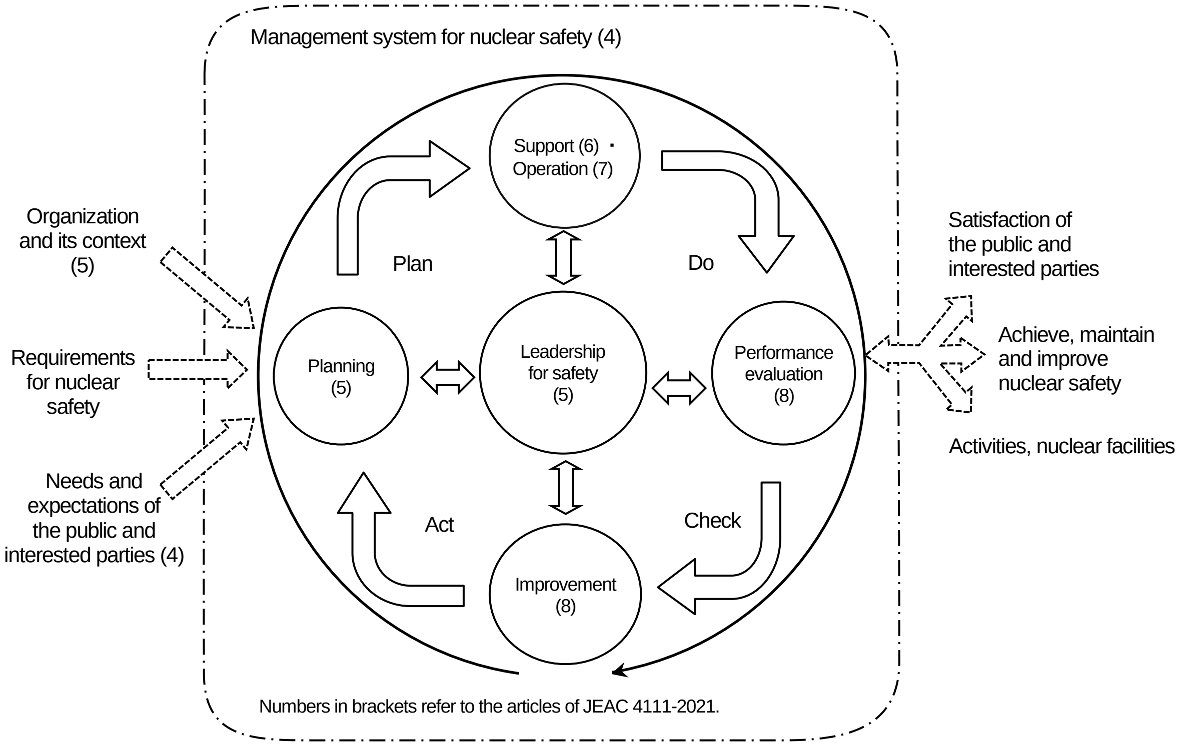
Quality management systems in nuclear power are based on ISO 9001 (JIS Q 9001), which is an international quality assurance code. They are characterized by the intention to achieve nuclear safety built on safety culture, management by grading (management according to the required safety and importance levels of products), independence of inspectors (strict inspection by personnel or divisions other than those involved in design or manufacturing), and verification in design control by those other than the original designers who actually did the designing.

This code is a direct requirement for nuclear power utilities and not a requirement for manufacturers. However, manufacturers have established quality assurance systems that reflect the requirements provided by the nuclear power utilities and are conducting quality assurance activities to comply with an annex to the code, Standard Quality Assurance Specification.

In the quality assurance systems of manufacturers, the customer is a nuclear power utility that the manufacturers provide with products or services. However, it is important for manufacturers to conduct quality assurance activities while bearing in mind that the achievement of nuclear safety through the nuclear power utility is the goal. In other words, achieving nuclear safety, not just serving for short-term benefits to the customer, will lead to true benefits to the customer.

Manufacturers are also working on overseas nuclear power plants and preparing required quality management systems, as represented by the safety regulation system of the U.S. NRC (*1).

*1: NRC: U.S. Nuclear Regulatory Commission




Note: The above English words have been translated from the original Japanese text of JEAC4111-2021 by JEMA, The Quality Assurance Committee for Nuclear Power Plants

Fig. II-1-1: Model of Quality Management System for Nuclear Safety

JEAC 4111-2021, Management System Code for Nuclear Safety, The Japan Electric Association

## 2. History of Quality Assurance Codes

As a guideline to quality assurance of nuclear power plants, the Japan Electric Association established the “Guide for Quality Assurance of Nuclear Power Plants” (JEAG4101-1972) in 1972 while referring to the Code of Federal Regulations (10 CFR 50 Appendix B). Afterward, the guideline was issued as the “Quality Assurance Policy for Nuclear Power Plants” (JEAG4101-1981) on the basis of the “Code of Practice for Quality Assurance for Safety in Nuclear Power Plants” (50-C-QA) established by the International Atomic Energy Agency (IAEA), and then revised four times until 1993. The IAEA 50-C-QA was revised in 1996 and publicized as the “Quality Assurance for Safety in Nuclear Power Plants and Other Nuclear Installations: Code and Safety Guides” (50-C/SG-Q) in the same year. Following this revision, the guidelines were modified again on the basis of the revision, taking into account the knowledge, experience and results in Japan and reflecting the operating status and results and eventually issued as JEAG4101- 2000. These guidelines, widely used by nuclear power utilities and suppliers (e.g., manufacturers) as quality assurance guidelines for nuclear power plants, made great contributions to the establishment of quality assurance systems and promotion of quality assurance activities.

The ministerial ordinances under the Reactor Regulation Law were revised in October 2003, and quality assurance requirements for nuclear safety were specifically stipulated to regulate nuclear power utilities. To embody these regulatory requirements for quality assurance, the “Quality Assurance Code for Safety in Nuclear Power Plants” (JEAC4111-2003) was established, and then JEAC4111-2009 was issued to incorporate ISO 9001:2008 revisions.

After that, the "Management System Code for Nuclear Safety (JEAC4111-2013") was issued in December 2013, based on the lessons learned from the accident at the Fukushima Daiichi Nuclear Power Station. Further, JEAC4111-2021 was issued, incorporating the latest knowledge from Japan and overseas. JEAC4111-2021 changed its position, specifying the requirements for strengthening activities that nuclear power utilities perform to achieve, sustain, and enhance nuclear safety based on international standards. JEAC4111-2021 has the following characteristics (see Figure II-2-1, Historical diagram of the quality assurance code system.)

a) Based on the International Atomic Energy Agency (IAEA) safety standards series (GSR Part 2), JIS Q 9001:2015, the U.S. regulatory system for nuclear energy, Atomic Energy Society of Japan (AESJ) Standards, etc., it defines fundamental requirements to comply with the QMS Regulation and its interpretation. It also includes additional requirements from the viewpoint of voluntary efforts incorporating the contents that contribute to safety enhancement.

b) It defines the significance of planning, including the use of risk information required in JIS Q 9001:2015, throughout the code.

Quality assurance requirements for manufacturers, as suppliers of nuclear power utilities, were determined in the “Guideline for Rules of Quality Assurance for Safety of Nuclear Power Plants (JEAC4111-2003) - Operating Stage (Annex to JEAG4121-2005, amended in 2007)”. They were revised later, incorporating the revision to JIS Q 9001:2015. Currently, these requirements are integrated into Annex 4 to JEAC4111-2021, “Standard Quality Assurance Specification Concerning Quality Management Systems” (for reference), contributing to enhanced quality of procured items.

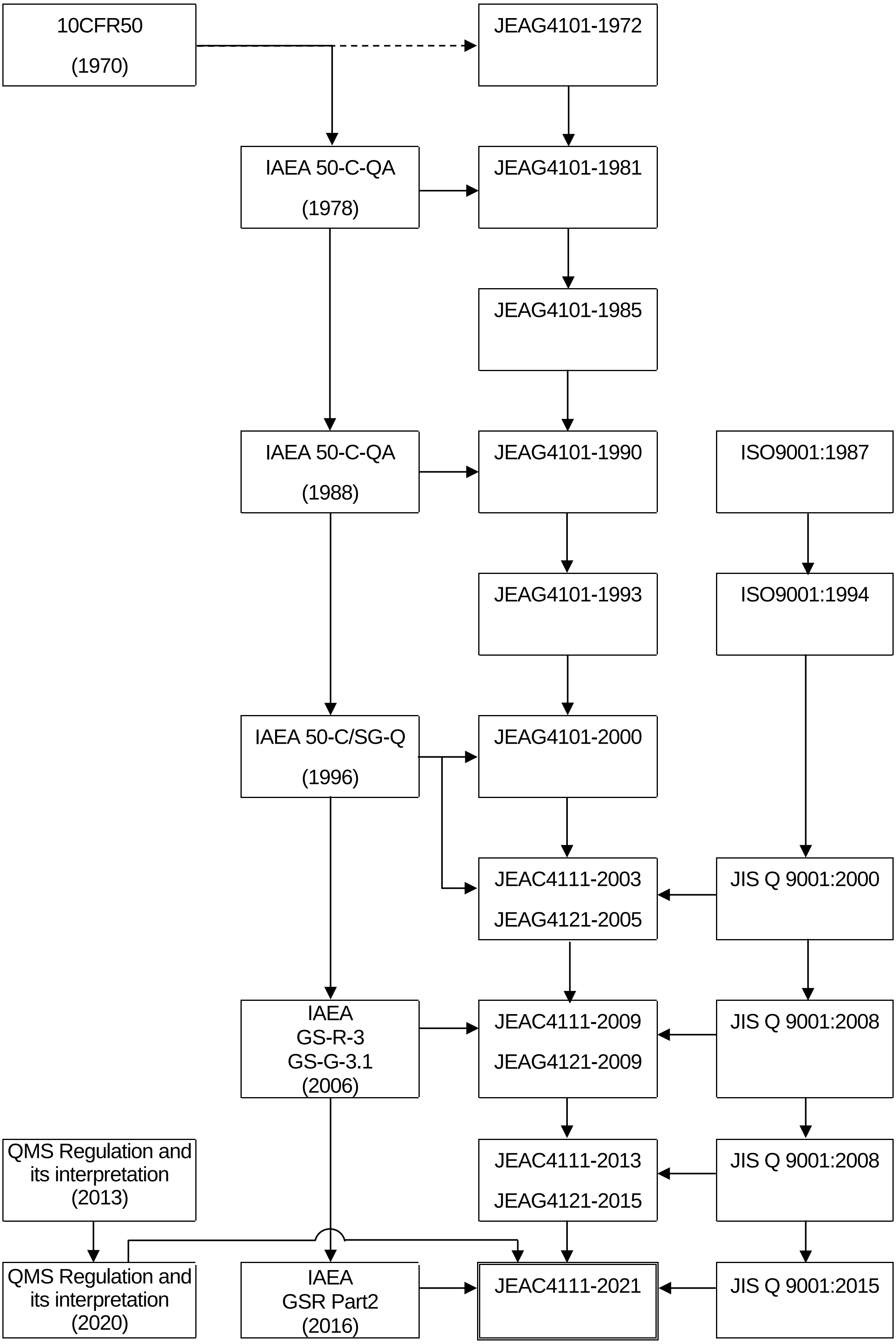



Fig.II-2-1: Diagram of changes in the quality assurance code system

# Ⅲ. Specific quality assurance

## 1. Context of the organization

A quality management system is a system that determines policies, sets objectives, conducts activities to achieve them, and continuously improves its effectiveness.

To build and operate a quality management system, organizations understand the context of the organization and the needs and expectations of interested parties and determine the scope of quality management. Then, the organizations have established, documented, implemented and maintained their quality management systems as described in the items below, have followed the PDCA (plan-do-check-act) cycle, and have continuously improved the effectiveness of the quality management systems.

(1) Understanding the organization and its context

The organizations determine external and internal issues relevant to quality around them and develop business strategies and policies to provide products and services that meet customer satisfaction and requirements. In addition, the organizations providing products and services related to nuclear safety think of "safety culture" as an issue they address.

(2) Understanding the needs and expectations of interested parties

The organizations identify direct customers and relevant interested parties to provide products and services that meet customer and applicable regulatory and statutory requirements. The organizations monitor the requirements of these interested parties from customer needs, expectations, degree of satisfaction, and others.

(3) Determining the scope of quality management system

The organizations consider external and internal issues, the requirements of the relevant interested parties, and their products and services to establish the scope of their quality management systems.

(4) Establishing, implementing, maintaining, and continuously improving the effectiveness of the quality management system and its processes

a) Determine the inputs required and the outputs expected from these processes.
b) Determine the processes needed for the quality management system and their application throughout the organization (quality management system diagram).
c) Determine the sequence and interaction of these processes (quality management

system diagram).

d) Determine the criteria and methods needed to ensure the effective operation and control of these processes.
e) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes.
f) Assign the responsibilities and authorities for these processes.
g) Address the risks and opportunities as determined in accordance with the requirements.
h) Evaluate these processes and implement changes needed to ensure they achieve their intended results.
i) Improve these processes and the quality management system.

(5) Quality Manual

The organizations prepare and maintain their quality manuals to meet the requirements of Annex 4 to JEAC4111-2021 while JIS Q 9001:2015 does not require organizations to do so.

(6) Grading

In operating their quality management systems, the organizations grade the degree of application of quality management system requirements according to the importance of products in terms of nuclear safety. An example of basic policy for grading according to the importance of products in terms of nuclear safety is the “Examination Guide for Classification of Importance of Safety Functions of Light Water Nuclear Power Reactor Facilities.” The “Guide for Design and Instrumentation & Control Equipment with Safety Functions (JEAG4611)” and the “Guide for Grade Classification of Electric and Mechanical Equipment with Safety Functions (JEAG4612)” are also used as references.

## 2. Activities to foster a safety culture

Safety culture is a term that became widely known in the wake of the 1986 Chernobyl Nuclear Power Plant accident, which pointed out problems with safety awareness in the background of the accident.

The International Atomic Energy Agency (IAEA) defined it as “the assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance.” In other words, when achieving, maintaining, and improving nuclear safety, it is affected by a safety culture. The leadership of everyone involved in the nuclear power business fosters a sound safety culture.

With lessons learned from the accident at the Fukushima Daiichi Nuclear Power Station and other experiences, manufacturers perform various activities to foster a safety culture. They understand the significance and social impacts of nuclear installations and ensure compliance with their rules in addition to laws, regulations, codes, and standards to foster a culture that places nuclear safety as the top priority.

For example, manufacturers carry out these activities to foster a safety culture considering the following elements:

<Safety culture 15 elements>

(1) Commitment of top management

(2) Clear policies determined and carried out by senior management

(3) Measures to avoid wrong decisions

(4) Questioning attitude

(5) Reporting culture

(6) Good communication

(7) Accountability and transparency

(8) Compliance

(9) Learning organization

(10) Efforts to prevent accidents and other events

(11) Self-assessment and independent assessment

(12) Work control

(13) Change control

(14) Attitude and willingness

(15) System to preclude falsification

## 3. Leadership

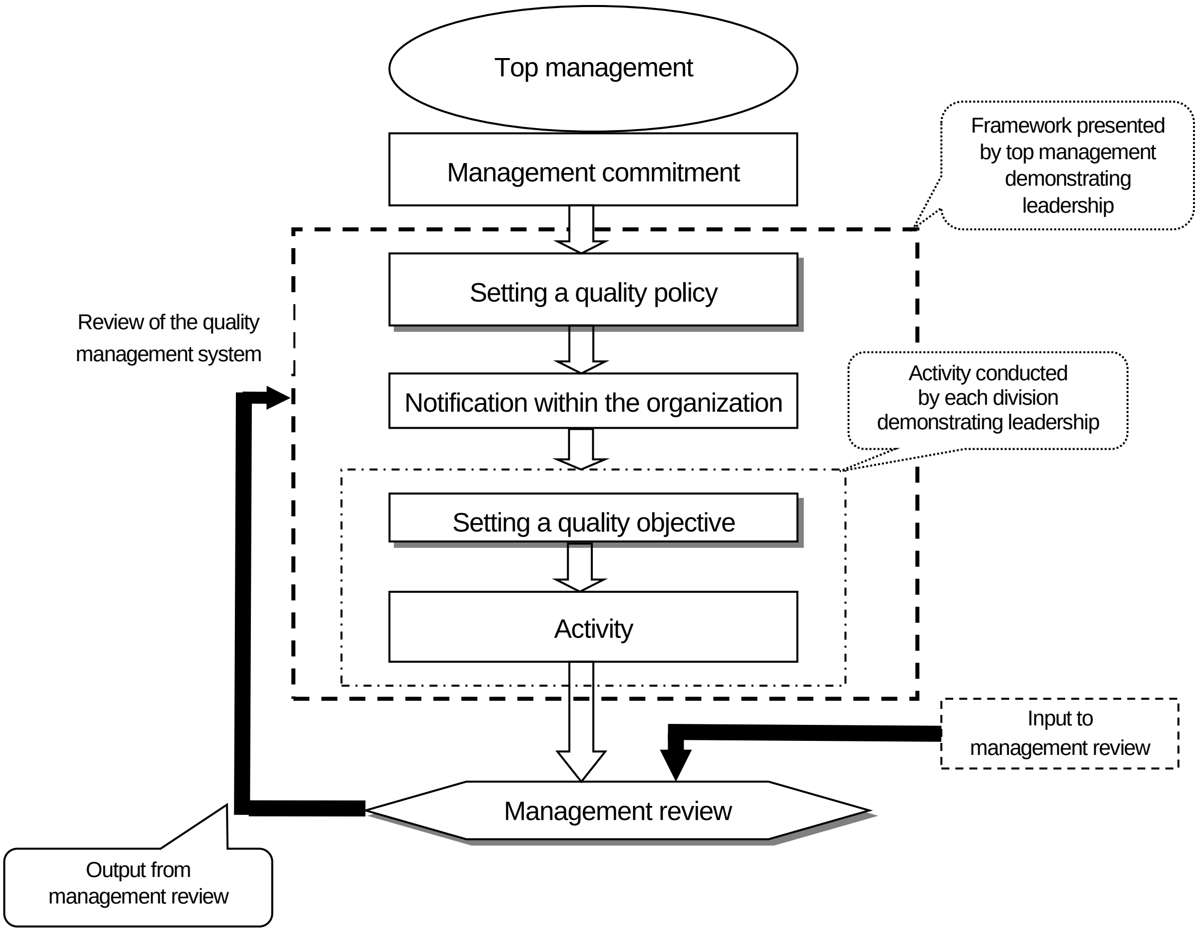
Efforts to foster a sound safety culture are inevitable to achieve, maintain, and improve nuclear safety. Leadership demonstrated by individuals in the organization for nuclear safety makes a safety culture a reality. As values guide their behavior, decisions need strong leadership in all positions.

The QMS Regulation defines "leadership for nuclear safety" as "the ability to play a leading role in understanding the significance of ensuring nuclear safety and in establishing the organizational quality policy and quality objectives for the personnel (i.e., meaning persons performing activities for safety; the same shall apply hereafter) to achieve them, as well as in setting the organizational vision for safety culture in which the individuals can take initiatives to foster and maintain a sound safety culture." The top management of nuclear power utilities should be committed to addressing issues regarding nuclear safety and protection as a top priority and demonstrate leadership to ensure decision-making at all levels aligned with nuclear safety.

Manufacturers that provide items and services of importance to safety for nuclear installations have declared “quality policies” as their commitments on the basis of their corporate philosophy and guidelines for achieving “nuclear safety” and fostering the underlying safety culture. Manufacturers should set goals and vision to raise the standard regarding nuclear safety, pre-determine the responsibility, authority, and chain of command at all levels in the organization for the activities performed by the individuals and organization to exercise effective leadership for nuclear safety and get them involved in the organization's activities and foster a sense of responsibility. Not solely top management but also division managers should demonstrate and exercise leadership to achieve and maintain nuclear safety in addition to the fundamental requirements from JIS Q 9001:2015 within the given responsibility and authority. As a representative of top management, division managers should perform the following activities as expected:

a) Set quality objectives based on the organization's quality policy. Monitor and measure the performance of duties to see the achievement.
b) Encourage individuals to raise awareness of and proactively address nuclear safety.
c) Communicate reliably the basis for decisions relevant to nuclear safety and the details to the individuals involved.
d) Encourage individuals to keep questioning and learning attitudes and proactively report issues on nuclear safety.
e) Encourage individuals to contribute to work improvements on their own.

Management also reviews how these activities are performed and fulfilled, as appropriate.




**JEMA Nuclear Safety Action Guidelines (excerpt)**

1. Maintenance and improvement of nuclear safety awareness
2. Review of operations
3. Enhancement of audit, and conduction of audit and evaluation by a third party
4. Sharing of information between nuclear related companies
5. Clarification of countermeasures and support measures in case of emergency

**JIS Q 9001:2015**
**Seven Quality Management Principles**

Principle 1: Customer focus
Principle 2: Leadership
Principle 3: Active involvement of people
Principle 4: Process approach
Principle 5: Improvement
Principle 6: Decision making based on objective facts
Principle 7: Relationship management

Fig. III-3-1: Leadership of top management in quality management practices

## 4. Planning

(1) Actions to address risks and opportunities

Manufacturers have established quality management systems to achieve their quality policies and objectives. To do so, manufacturers as suppliers should also pursue customer satisfaction from nuclear power utilities. It turns out that the manufacturers' business environment affects the effectiveness of their quality management systems to no small extent.

For that reason, manufacturers seek to develop a better plan for quality assurance, considering measures against problems that occurred and risks listed for preventing possible problems. Manufacturers can also identify new opportunities for improvement in the course of efforts to address the issues according to the plan.

Taking these risks and opportunities, manufacturers narrow down problems most likely to occur and those with potentially significant impacts, then implement intensive measures.

(2) Quality objectives and planning to achieve them

Manufacturers set their quality objectives by reflecting quality policies, evaluation results of management reviews, etc., and also set objectives at necessary subordinate organizations or hierarchical layers for more effective operation. Each manufacturer encourages the organization members to deepen their understanding of the objectives by clarifying the position of the quality objectives within the activity objectives of the entire organization to create an environment suitable for the members' activities.

As organizations, manufacturers set indexes for the status of and plan for objective achievement. The point is that the objectives allow judgment of the level of achievement of targeted value. Quantifying target values is not a requirement. Manufacturers determine what will be done, who will be responsible, how the results will be evaluated, etc., to develop a plan for achievement.

In addition, when evaluating the achievement status, manufacturers evaluate not only the result but also the levels of effort and commitment toward achieving the objectives, so as to maintain motivation.

(3) Planning of changes

Changes to the quality management system are needed for various reasons, for example, handling external issues, such as changing business environment and requirements from interested parties, and internal issues, such as changes to work processes and evaluation results from management reviews.

When making changes to the quality management system, manufacturers determine the purpose for the changes and impacts caused by the changes to implement the changes in a planned manner.

## 5. Competence, Awareness, Education, Training, and Organizational Knowledge

Humans are the most important element of managerial resources not only in manufacturers, but also in other types of companies. To develop an organization, it is essential to establish an education and training structure for enhancing the abilities of individuals and to efficiently pass on skills. Manufacturers intend to maintain and improve the knowledge, experience and technological capabilities required to accomplish their operations by conducting competence management, education and training in a planned and systematic manner for personnel engaged in operations that may affect product quality. In addition, manufacturers manage designers, design reviewers, design verifiers, inspectors, internal auditors, etc., by establishing internal qualifications, certifying those with experience, skill and knowledge above a certain level, and registering them on a list of qualified personnel.

Concerning competence evaluation, the manager at each division manages the proficiency levels of personnel within the division regarding elemental skills required for the operations of the division by preparing a map that quantifies proficiency levels (elemental skills map) in each fiscal year. Using the elemental skills map, the manager formulates an annual education plan for each person after identifying his or her strengths and weaknesses. Meanwhile, personnel recognize their current skill levels through interviews with the manager or other means in an effort to cultivate themselves. In addition, the manager evaluates the effectiveness of personnel education and training from attendance reports and other education records as well as progress in daily duties.

Education and training conducted are organized into such areas as layer-specific education, quality management education, specialty education, qualification education, preassignment education, ethical improvement education, re-education/re-training and OJT (on-the-job training). The forms of education include company-wide training, divisional training and external training. The manager formulates long-term and short-term education and training plans for each person in accordance with the elemental skills map, tracks the status of implementation of the plans, and records and maintains an education and training history for each person.

The organization determines the organizational knowledge necessary for operating its processes and to achieve conformity of products and services. This knowledge is maintained and made available to the extent required, based on internal sources (e.g., intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services); and external sources (e.g., standards; academia; conferences;

gathering knowledge from customers or external providers).

Some characteristics of the field of nuclear energy are described below.

a) In the field of nuclear energy, nuclear safety is especially important. Manufacturers therefore conduct nuclear safety education and compliance education for thorough understanding of the importance of law compliance and corporate ethics.

b) As for designers, manufacturers extensively cultivate them as system engineers in addition to having them learn advanced elemental skills through specialized education. As regards technicians, manufacturers certify those who have received education and training on key basic operations such as screw tightening, terminal crimping and soldering. Concerning skills in special processes such as welding, heat treatment and nondestructive inspection, manufacturers provide education and training to workers for skill certification and periodic updating. Those who engage in operations requiring official qualification, such as slinging work and hazardous material handling, are also registered on the list of qualified personnel. As for workers engaged in pre-operation, manufacturers intend to improve their technical capabilities by providing simulative operation training or the like at training facilities in addition to ordinary education for deepening their understanding of the entire plant.

c) Because installation and modification work and periodic inspection on site are extensively performed, manufacturers cultivate highly skilled instructors and dispatch them to the site, and provide education regarding general nuclear, specialties and radiation safety to all workers engaged in site work before they are dispatched to the site. In addition, at the site, manufacturers provide education to workers at the time of their entering the plant, including quality control and radiation control, and before starting their work, and provide daily education through toolbox meetings (TBMs), etc.

## 6. Control of Monitoring and Measuring Equipment

Manufacturers clarify the measurement instruments (calipers, micrometer, etc.) and monitoring equipment (e.g., ammeter used for welding) that must be controlled by specifying them in control manuals, procedures, etc.

To maintain and secure the accuracy of such measuring and monitoring equipment, manufacturers also clarify the following specific steps and methods for each piece of equipment to be controlled, by specifying them in control manuals, procedures, etc.

a) Identification control using control numbers, etc.
b) Equipment calibration expiration date and calibration interval
c) Specific calibration method including technical elements at the time of calibration
d) Specific action in case of deviation from the equipment calibration criteria
e) Storage site and environment

Measuring equipment used for assessing inspection or test results is calibrated or verified in accordance with a metering standard traceable to an international or national measurement standard. Measuring equipment for measuring test conditions, for example, may also be treated as “measuring equipment used for assessing results” if it is judged to be important for the assessment, even if it is not directly used for assessing inspection or test results.

Concerning the “traceability control” of measuring equipment, the manufacturer confirms linkage to the extent that a standard that complies with the inspection system for standards under the Measurement Act can be traceable to a “traceable metering standard” indicated below.

<Traceable metering standard>

a) A meter owned by a national measurement standard laboratory
b) A meter that is owned by a certified business operator in accordance with the certification system for calibration business operators (JCSS) within the scope of certification defined by the Measurement Act and a meter calibrated within the scope of the certification by a certified business operator in connection with the former meter
c) A meter that is owned within the scope of certification by a calibration business operator certified by a certified testing organization that has signed the international mutual recognition (MRA) provided by the recognised regional cooperation bodies, such as the International Laboratory Accreditation Cooperation (ILAC) and the Asia Pacific Accreditation Cooperation (APAC); and a meter calibrated within the scope of certification by a certified business operator in connection with the former meter

Reference: NQA2007001-0, Guideline for Traceability of Measuring Equipment at Nuclear Installations (Report for Discussion), the Japan Electrical Manufacturers' Association (JEMA)

When using computer software for monitoring and measurement, manufacturers confirm its ability to achieve the intended monitoring and measurement before the first use.

## 7. Control of Documents and Records

### (1) Control of Documents

Documents required for the quality management systems are controlled, excluding records, a kind of documentation but controlled to meet the requirements defined in "Control of Records." "A documented procedure" is established to define controls applied to the following activities:

a) Approve a document before issuing it from the viewpoint of whether it is appropriate.
b) Review documents, then update and re-approve them as necessary.
c) Identify changes to the document and ensure the current version can reliably be identified.
d) Ensure the appropriate version of an applicable document is available where and when needed.
e) Ensure documents are legible and readily identifiable.
f) Identify documents of external origin that the organization determines necessary for the planning and operation of the quality management system and ensure that their distribution is under control.
g) Prevent obsolete documents from being mistakenly used. If it is necessary to keep them for some purpose, identify them appropriately.

### (2) Control of Records

Manufacturers control records prepared to provide evidence of conformity with the requirements and effective operation of the quality management system.

The organization has established "documented procedures" to define necessary controls over records for identification, storage and preservation, protection, retrieval, retention time, and disposition.

Records are legible, easily identifiable, and retrievable.

（Reference 1）

Generally, there are three ways of storing records: storing and controlling original paper records; storing and controlling originals in an electromagnetic way; and storing and controlling originals by using the former two methods simultaneously.

The following describes a typical procedure in which the originals are stored and controlled in an electromagnetic way.

a) The original paper records to be controlled are digitized and registered using a device such as a scanner.

b) The digitized data is compared with the original to check that it contains no missing pages, leaning, smudge, blur, etc., and can be read correctly.
c) The originals are provided with identification such as indexes so that they can be promptly retrieved for reference and stored and controlled in a storage place under appropriate temperature, humidity and other conditions for preventing the records from being deteriorated, according to the classification of whether the records are stored permanently or temporarily.
d) That the digitized data is correctly registered is confirmed by accessing the digitally registered data once again.
e) From the viewpoint of preventing records from being lost due to disasters, accidents, etc., a dual record storage and control structure should be established, such as locating the storage of originals and the storage of digitized data at sufficiently distant places or storing digitized data in two separate places that are sufficiently distant from each other.

（Reference 2）

Control of quality records in nuclear power plants has traditionally been conducted by plant manufacturers and other companies involved under requirements defined in notifications from the NRA and common policies defined by related laws and regulations as well as codes and standards such as those of JEAC.

## 8. Customer-Related Processes

Customer-related processes refer to preparing necessary documents to meet customer requirements, communicating with customers, submitting deliverables, and providing customers with satisfaction. Specific customer-related processes used by manufacturers are as follows.

(1) Preparation of plan

The manufacturer prepares a plan that specifies the project process including the relevant statutes/codes/standards, implementation scheme, implementation items, content, delivery date, schedule and estimate conditions in accordance with the specification of requirements provided by the customer.

In the time schedule attached to the plan, the manufacturer stipulates, for each item, related implementation divisions, hold points set with the customer and designated by the coordinating division, and the like.

(2) Kick-off meeting with the customer (confirming/adjusting the implementation details, schedule, etc., with the customer before starting the work)

The manufacturer holds a kick-off meeting with the customer before commencing the work by using a plan or the like for confirming and coordinating hold points with the customer to check whether the work plan has any problem.

(3) Preparation of work procedures

Before performing the work, the manufacturer prepares work procedures that specify detailed work methods and steps (e.g., input data, work procedure/method, cross-divisional items, work schedule, check procedure, check sheet) and receives confirmation or approval from the customer.

(4) Checking with hold points with the customer

The manufacturer organizes matters requiring approval of the customer using hold points set with the customer in the plan and receives confirmation or approval from the customer.

(5) Checking the implementation result

In preparing a report, the manufacturer specifies the period for preparing a draft report (including the checking period), internal review period, draft report correction period, report submission deadline, etc.

Before double-checking the implementation result, the manufacturer reconfirms the checking procedure defined in the work procedures. In addition, the manufacturer secures a sufficient period for reviewing prepared documents, and conducts an overall review. The manufacturer checks the checking method and the like based on evidence, validates the check process, and submits a report to the customer.

(6) Evaluation by the customer

To grasp how the customer evaluates the manufacturer, a direct interview with the customer and other methods are being used.

The manufacturer collects evaluation data from the customer by, for example, directly interviewing the customer for opinions and requests, accepts the customer's inputs with sincerity as valuable feedback, and makes use of them in improving future activities.

## 9. Design and Development

Activities conducted at the design and development stage aim to meet the customer requirements and the applicable statutory and regulatory requirements. Basically, they consist of: (1) formulation of design and development plans; (2) control of design and development inputs/ outputs; (3) review, verification and validation of design and development; and (4) control of changes in design and development (*1).

In formulating a design and development plan, design and development stages, design interfaces between organizations, reviews appropriate for each stage, and methods and timing of verification and validation must be specified. In doing so, the manufacturer adopts a grading approach according to the complexity of design and development, novelty, importance of equipment and assumed risk. In particular, if a special material or new technology for which no official standard is defined is adopted, it is required to exchange information between the parties concerned (customer, supplier, etc.) as necessary, in addition to conducting examination, so that the meaning and importance of the material specifications, technical contents, etc. are fully understood. The manufacturer reflects such information in the design and development plan (*2). In a review of design and development, the manufacturer confirms that the design and development results meet the requirements and makes an evaluation from diversified viewpoints with the participation of specialists in the respective fields.

Verification of design and development is conducted through design and development reviews, alternative calculations, manual calculations, demonstration tests, comparison with similar designs, checking of design documents, etc., by someone other than the original designer. For analyses concerning collation of the Design and Construction Plan, application for permission, etc., the manufacturer specifies the required verification procedures for control, such as checking collation by a third party, in addition to verifying the computer programs used.

Validation of design and development must be completed before using them. It is conducted, for example, in performance tests at the factory, performance tests at the stage of installation at the nuclear power site, and during pre-operation before the start of operation.

Changes in design and development are made using a design control method equivalent to that used for the original design. In addition to reviewing, verifying and validating the changes, the impact of the changes on the products already delivered is evaluated.

*1: JIS Q 9001:2015 describes requirements more simply, for example, design and development planning, design and development controls, and design and development changes, but manufacturers perform the activities in compliance with JIS Q 9001:2008 requirements.

*2: Incorporating a lesson learned from the falsification of data on the boron concentration of a neutron shielding material inside a spent fuel cask

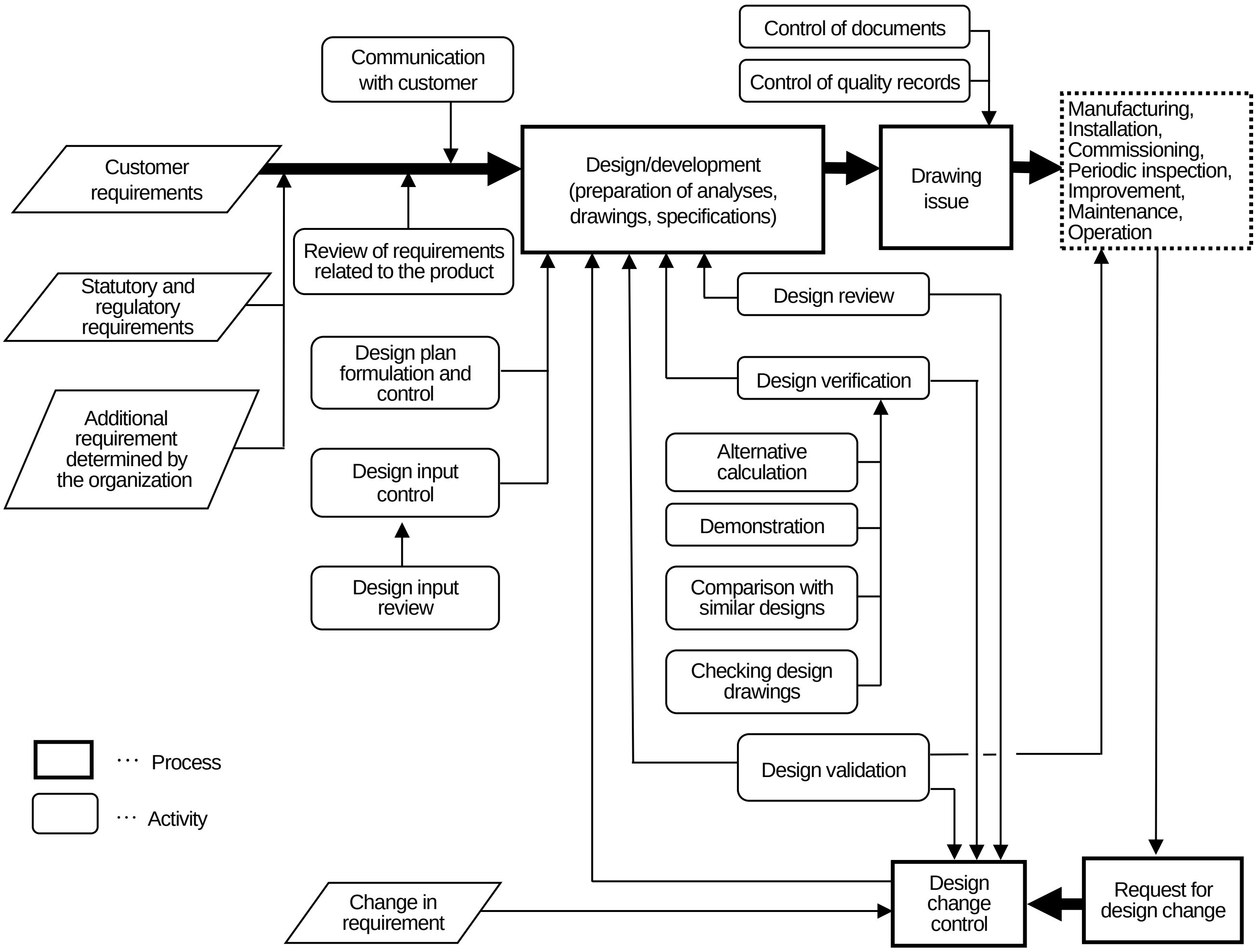



Fig. III-9-1: Flow of design and development control

## 10. Procurement Control

Before procuring products for a nuclear power plant, it is important to:

- clarify quality requirements in the procurement documents,
- evaluate suppliers' abilities to manufacture products and establish a smooth cooperative relationship with the suppliers, and
- establish control systems for products to be procured.

Orderers also strive to facilitate liaison and coordination with suppliers (contractors) by, for example, checking whether the procurement schedule is unreasonable and would affect the quality (*1).

Figure III-10-1 shows the flow of product procurement operations. The procurement of products for nuclear power plants is distinctive as follows:

- Products important to safety are inspected by the licensee according to the Reactor Regulation Law (*2).
- Since complicated products that are completed through a number of processes are difficult to check for conformity to their requirements by inspection at the final product stage only, manufacturing procedures are prepared so that the products can be inspected at predetermined intermediate checkpoints.
- Prior to manufacturing, manufacturers review and discuss the design together with suppliers to confirm that any improvements and changes to the preceding plants are taken into consideration and that any problems in domestic and overseas plants are taken into account.
- If manufacturers adopt a new design or construction method that is made available through technological development, they should begin discussion with suppliers at an early stage in order to identify possible problems and realize smooth introduction.
- When procuring special materials for which no official standard has been defined, manufacturers intend to secure the quality of such special materials by adding requirements for controlling the issuance of a material certificate, checking the original data, etc. (*1).

In addition to these activities, the organization takes actions to preclude counterfeit and fraudulent items so that such items are unused in nuclear facilities under appropriate supply chain management. The organization also shares information with interested parties on counterfeit, fraudulent, or suspicious items if detected.

*1: Incorporating a lesson learned from the falsification of data on the boron concentration of a neutron shielding material inside a spent fuel cask

*2: Inspections by the regulator were changed to inspections by the licensee with the amendment to the Reactor Regulation Law (i.e., the inspection system was revised).

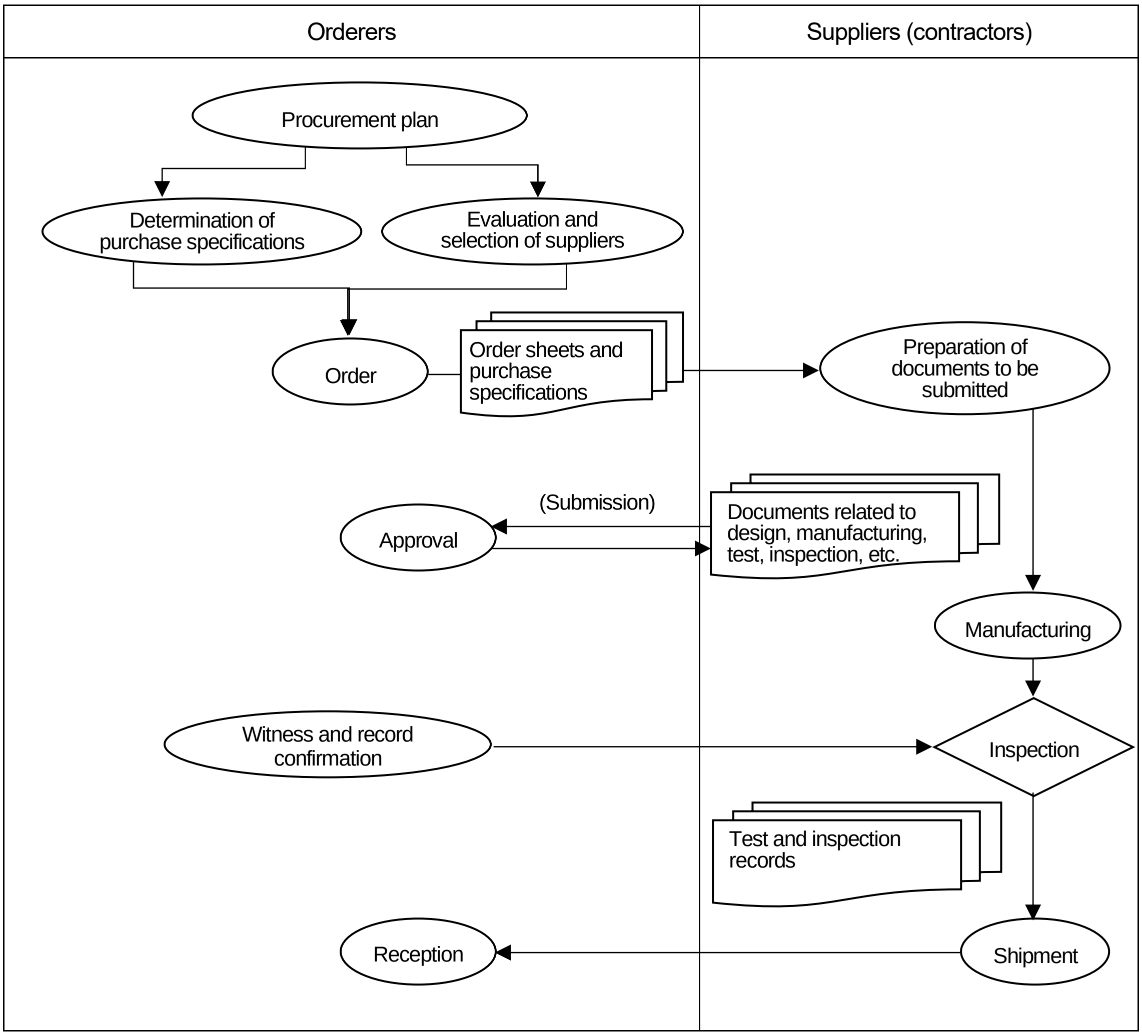



Fig. III-10-1: Flow of procurement control

## 11. Production and Service Provision

(1) Manufacturing Control

The most important aspect of manufacturing control is to ensure quality in the manufacturing process. Therefore, design requirements must first be clearly identified by means of documents, drawings, etc. Manufacturers strictly comply with codes, standards, procedures, instructions, drawings, etc., to fulfill the design quality.

Quality control of manufacturing in nuclear energy is conducted as follows.

a) Planning and preparation

Planning is important for manufacturing. Therefore, manufacturers formulate work standards, and organize construction methods and work procedures in the form of instructions. These instructions include a QC process chart or manufacturing procedure drawing where hold points are set. In particular, when adopting an innovative technique, manufacturers carefully study it.

Before starting work, manufacturers hold meetings among the parties involved for confirming the construction method and work procedures.

b) Work environment

Establishment and improvement of the work environment are widely practiced as a "5S" movement. 5S stands for Seiri (orderliness), Seiton (neatness and tidiness), Seiso (cleaning), Seiketsu (cleanliness), and Shitsuke (good manner). In addition, manufacturers make efforts to improve occupational health and safety such as securing lighting, reducing noise and removing hazardous substances.

In many cases, stainless steel is used for nuclear industry products. To prevent stainless steel from being corroded, manufacturers set work zones, maintain cleanliness, control temperature and humidity, prevent dust and foreign material intrusion, and restrict the components contained in subsidiary materials.

In addition, manufacturers may control temperature, humidity, etc., as necessary in order to prevent electric parts from being deteriorated.

c) Facilities, devices, jigs/tools, and measuring instruments

Appropriate facilities, devices, jigs/tools, and measuring instruments are used because they significantly affect quality. It is important to maintain and control them in order to secure the prescribed functions and accuracy, and therefore manufacturers conduct prework and periodic inspections.

d) Identification and traceability

(i) Identification

Various materials and parts are present at a manufacturing site. To avoid improper use and confusion, manufacturers manage identification of such items. Identification methods are defined in procedures or the like, and practices such as indicating unique numbers using tags, stamps, etc., are performed. Care is taken to protect these marks from being erased. If a material is divided, its identification will be transferred accordingly.

Concerning the indication of the state of products, manufacturers identify whether the inspection is completed, whether the inspection result is satisfactory, and any nonconforming products.

(ii) Traceability

If a problem occurs with a product while the customer is using it after being delivered, it may be necessary to trace back the cause to the manufacturing stage and take some measures. Therefore, manufacturers should maintain a manufacturing history and use it to enable any nonconformity to be traced back to the time and process where it occurred. In particular, in cases where there are statutes, rules or customer requirements, manufacturers should ensure that the product history can be traced.

At the manufacturing stage, manufacturers record the date/time, workers and manufacturing equipment used in a work report or the like so as to allow their identification. Manufacturers keep a series of manufacturing records to allow parts to be traced. Materials can be traced in material certificates (Mill sheets) with identification marks.

e) Competence, education and training of workers

Manufacturers improve the skills of workers through education and training. There are operations requiring workers with official qualifications such as crane operation, slinging work and organic solvent handling, and those who have acquired the required qualification engage in such operations.

When necessary, manufacturers limit nut and screw tightening, crimping and soldering operations to in-house qualified personnel who have been trained for key basic operations.

f) Implementation of operations

Workers perform operations in accordance with procedures or instructions. Manufacturers strive to secure the safety of workers by routinely holding toolbox meetings, etc., rechecking procedures and conducting risk prediction.

To prevent nonconformities caused by humans, manufacturers take actions to prevent human errors and perform hazard prediction activities for construction management staff and workers according to the degree of impact on products.

Manufacturers address those works of 3H matters (i.e., Hajimete for the first time, Henko after change, and Hisashiburi after long intervals), reconfirming work descriptions and procedures with due consideration of human errors.

g) Schedule coordination

Manufacturers coordinate schedules at periodic schedule meetings and the like so that the schedules will not adversely affect the achievement of the required quality.

h) Shipping

Manufacturers ship products after completing all work, tests and inspections determined at the manufacturing stage. Before the product is shipped, final checks are performed, and a person responsible for shipping checks the result and issues a shipping permit.

i) Process validation (special process)

If an output at the manufacturing stage cannot be verified by the subsequent monitoring or measurement, it is necessary to demonstrate somehow that the planned result can be achieved. Manufacturers secure the required quality by confirming that the operation is performed with a correct method. In particular, manufacturers regard welding, heat treatment, cleaning, surface treatment, etc., as special processes and validate these processes. In addition, manufacturers validate an innovative technique when adopting it.

To secure the reliability of these special processes, manufacturers should define in the work procedures the methods for controlling facilities, jigs, and tools, as well as work procedures based on existing know-how, etc., have well-trained or experienced adept workers do the work, and perform operations in accordance with these procedures. To achieve this, manufacturers check the work procedures in advance and check the qualification of personnel, facilities used, construction records, etc.

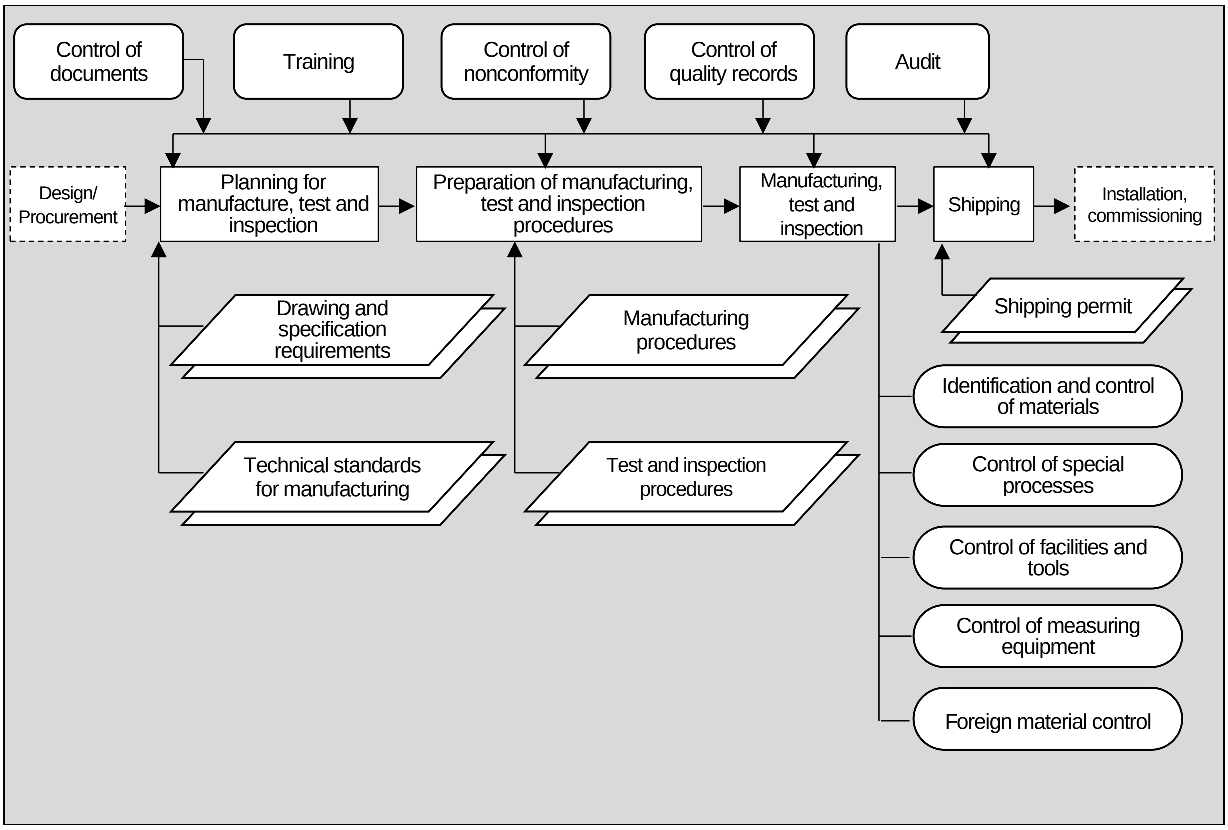



Fig.III-11-1: Flow of manufacturing control

(2) Control of Construction and Installation Work

Manufacturers control construction and installation work using methods similar to those for manufacturing control.

Various organizations and people such as nuclear power utilities, plant manufacturers, equipment/ device manufacturers, and builders are involved in the construction and installation work, and abundant and varied operations are performed concurrently. Therefore, it is necessary to establish a clear structure and ensure close interactions. To reliably achieve this, activities such as the following are conducted within or between organizations.

- QA/QC meeting
- Technical communication meeting
- Schedule coordination meeting
- QA/QC patrol
- Full check of installation
- QA audit

In addition, manufacturers systematically conduct education and training intended for improving the work environment and enhancing workers' safety and skills throughout the construction period in order to secure the required quality and operational safety.

Furthermore, manufacturers strive to streamline construction work by actively working on the improvement of construction methods so as to shorten construction periods, reduce construction costs, and secure quality and operational safety.

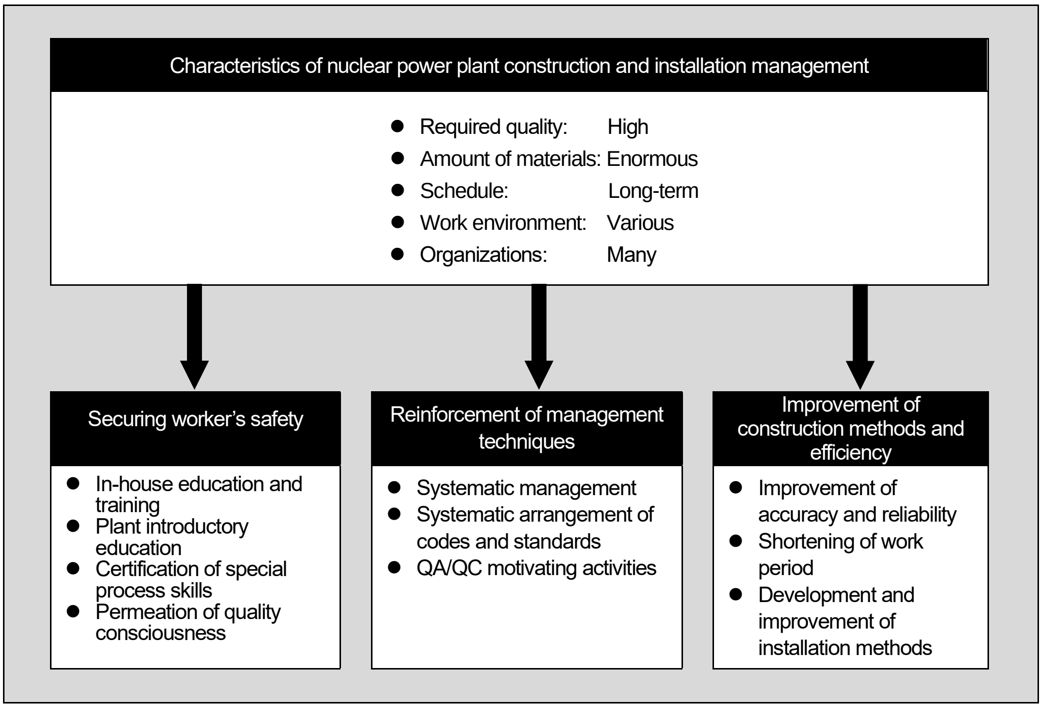



Fig. III-11-2: Key items of quality assurance activity at the installation stage

## 12. Monitoring and Measurement of Products

For a product delivered to a nuclear power plant, the manufacturer reliably conducts thorough inspections and testing that monitor and measure the product to ensure its conformity to the quality requirements, including nuclear safety.

The inspections and tests conducted at various stages from product design to manufacturing and installation are roughly divided into demonstration testing for verifying the design, inspection and testing at the manufacturing stage at the factory; and inspection, testing and pre-operation at the installation stage at the nuclear power plant.

With regard to the control of inspection and testing at the above-mentioned process stages, there are some critical points that need to be dealt with, such as test and inspection planning, preparation of written procedures, management of inspector and tester qualifications, calibration of monitoring and measuring equipment, and management of its handling, storage and use. These activities are controlled very strictly and thoroughly in nuclear power plants. Such controls also apply, for example, to establish hold points, verify the effectiveness of the monitoring and measuring equipment, and indicate inspection and test conditions.

The characteristics of product monitoring and measurement at a nuclear power plant include recording the result of acceptance judgment, and defining the degree of independence between the person responsible for the inspection and testing involving result judgment and the person responsible for the manufacturing, operation, etc., with the aim of securing the reliability of the inspection and testing.

The hold points above include pressure-resistance and leakage inspections by the licensee, characteristic tests, Licensee's Pre-Operational Inspections on welding and facility, and other inspections.

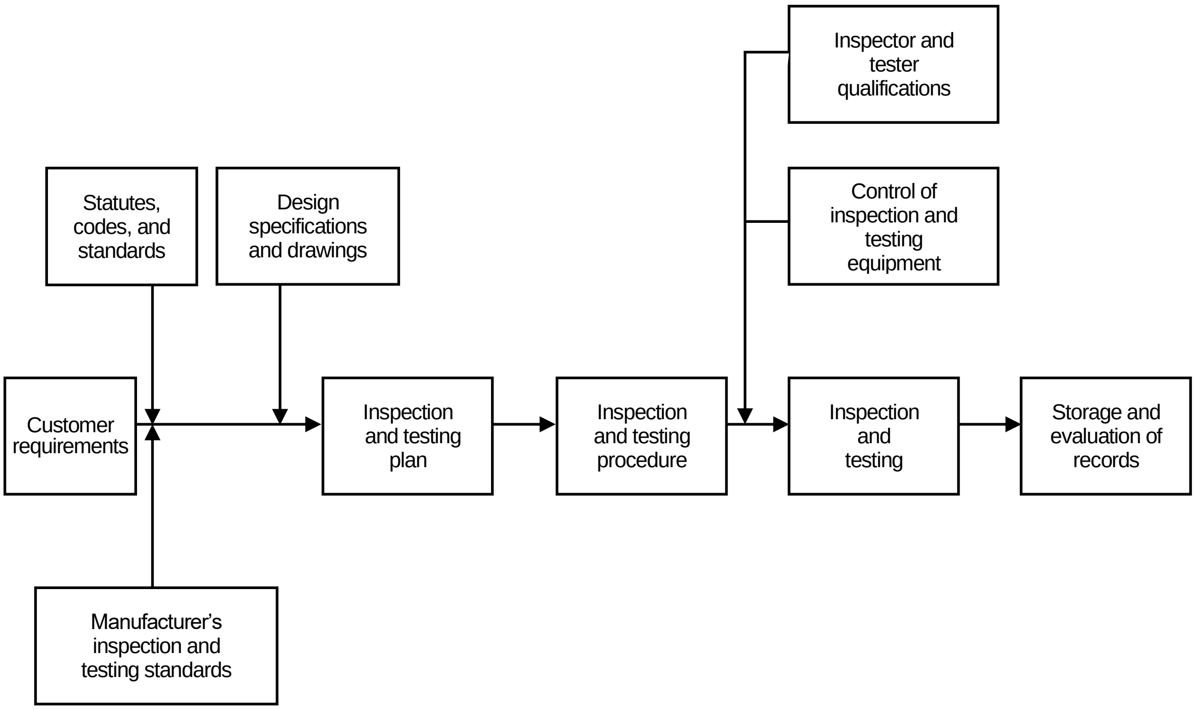



Fig. III-12-1: Flow of Inspection and testing control

## 13. Internal Audit

An internal audit is intended to check and evaluate a quality management system from the viewpoints of conformity and effectiveness and provide an opportunity for improvement. While conducting an internal audit is not itself an objective, manufacturers utilize it as a tool for enhancing their quality management systems.

In selecting auditors and conducting an internal audit, the manufacturer secures objectivity and fairness of the audit process, and the audit team confirms that all necessary improvements and corrective actions are taken against any nonconformity found in the audit.

When formulating an audit program, the manufacturer adopts the "grading" approach, and takes into account the state and importance of the process and area subject to the audit, past audit results, etc. In addition, for follow-ups conducted to check the implementation state of corrective actions, the manufacturer defines the timing and the method according to the importance of nonconformity.

The following are examples of strategies to effectively conduct an internal audit.

a) The auditing and audited parties mutually confirm the meanings of the matters indicated by the audit (weaknesses of the organization) and the necessity of improvement.
b) Make recommendations in order to spread good examples into other organizations.
c) Place focus also on problems found in other organizations and between multiple organizations, leading to improvement.
d) Specify key audit items for each audit in order to prevent auditing from getting into a rut.
e) Make efforts (enhancing education and training for auditors) to improve the competence of auditors.
f) Utilize the result of self-assessment by the audited organization as an input to the internal audit.

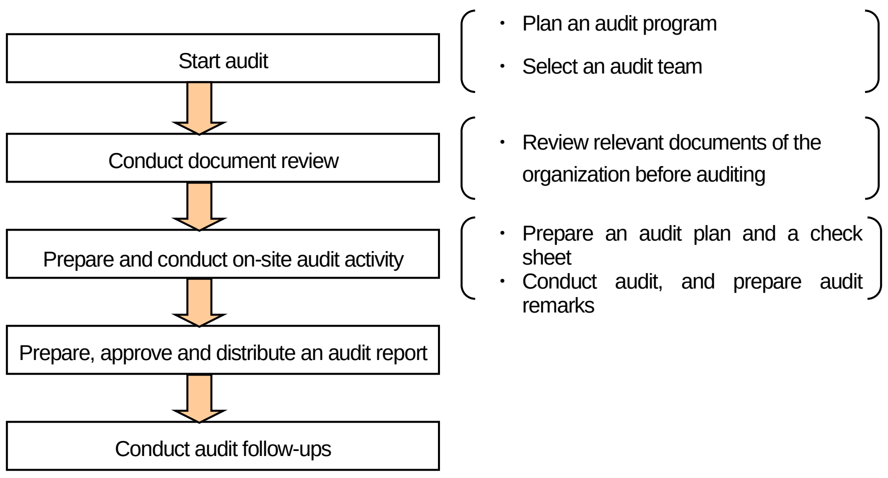



Fig. III-13-1: Overview of audit activity

## 14. Management Review

A management review is a means used by the top management to evaluate the effectiveness of the quality management system in order to respond to changes in the business environment, make necessary changes in “quality policies” and “quality objectives,” and provide an opportunity for improving the quality management system. The top management of each nuclear power utility and manufacturer (supplier) expresses, through the management reviews, their strong interest in achieving nuclear safety and quality assurance.

## 15. Control of Nonconforming Products

In quality assurance activities at various stages, from design and development to operation and maintenance, manufacturers perform quality assurance activities, ensuring that they are consistent with the requirements in drawings, procedures, instructions, etc., in advance. Then, the manufacturers proceed to the next step after verifying, at the prescribed timing, that the requirements are met.

In doing this, the manufacturers regard it as nonconforming when the product or service to be delivered is inconsistent with and does not meet the requirements (specification or instruction).

The manufacturers control nonconformities in accordance with a procedure that defines the following methods:

a) Method for reporting any detected nonconformities
b) Method for treating nonconformities (identification, removal, concession, disposal, etc.)
c) Method for re-verification in the case of correction of a nonconforming product
d) Control method for clarifying the causes of nonconformities and establishing and implementing measures to prevent recurrence
e) Recording method

If nonconformity is detected, the worker in charge discontinues the operation, and promptly reports to the supervisor. In addition, the manufacturer reports the nonconformity to the utility in accordance with an agreement with the utility.

A nonconforming product is provided with an identification that allows the nonconformity to be easily recognized, so as to prevent the product from being improperly used or mistakenly shipped. Methods for this identification include marking and tagging on a nonconforming product. As a treatment of nonconformity, deliberations are conducted by the supervisor at the responsible organization or concerned personnel to adopt an appropriate method. The following are examples of such methods.

- Correction: adjust, repair, or correct the nonconforming product so that it meets the requirement.
- Segregation, prevention from getting scattered and lost, returning, or stopping provision: identify any nonconforming product in order to prevent it from being used or adopted as originally intended, move it to another place, confine, isolate, and discard it if necessary.
- Notification to customers: notify customers of a significant nonconformity and things that may affect the schedule or other elements.
- Concession: judge that the state of the nonconforming product is acceptable, the customer and the supervisor of the organization give approval and accept it exceptionally, and the product is used as-is without disposal.

If a nonconforming product is adjusted, repaired or corrected, the manufacturer conducts testing and inspection again to re-verify the product.

Nonconformity is recorded in the form of a nonconformity report that describes the detection status, emergency action status, disposal method, reevaluation result, development of corrective action, etc.

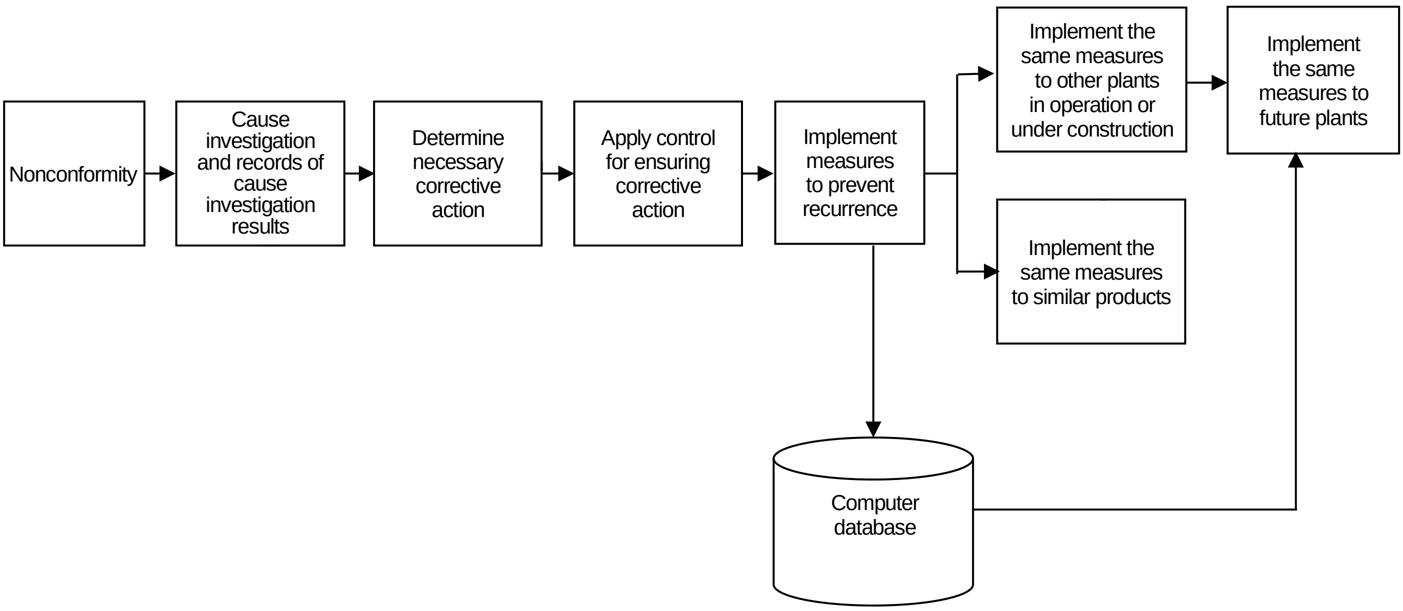



Fig.III-15-1: Flow of nonconformity control

In recent years, a materials and parts manufacturer shipped products tampered with, falsified, or otherwise improperly fabricated in the manufacturing and inspection process and delivered some of them to nuclear power plants. The organizational background is as follows:

- Its quality assurance organization is not assured of organizational independence.
- Its established corporate culture prioritizes delivery and sales profit.
- Awareness of quality compliance has faded.

Given the above, plant manufacturers and other companies take the following preventive measures for suppliers, considering the importance of the materials and components they provide and their track records.

a) Fostering a nuclear safety culture

- Perform awareness campaign activities for a nuclear safety culture and quality compliance using liaison conferences, exchange meetings, and other communication with manufacturers

- Share information on the cases of inappropriate conduct in nuclear energy
- Provide training materials on a nuclear safety culture, quality compliance, and others that plant manufacturers have.

b) Procurement requirements

- Require suppliers to control inappropriate conduct if identified and share information with the orderer.
- Require suppliers to allow access to the places and records related to the contract if there is a suspicion of inappropriate conduct.
- Check if required specifications are too strict and optimize them.

c) Confirmation during a supplier survey or others

- Product inspection system
- Implementation status of quality assurance program
- Implementation status of quality compliance training
- Controls of secondary and sub-tier suppliers
- Process capability (manufacturing capability)

d) Detecting inappropriate conduct

- Provide the individuals involved in plant manufacturer's quality management with training on the cases of inappropriate conduct.
- If there is a suspicion of inappropriate conduct, check inspection data, including the original data, determine whether the inspection uses the methods and facilities complying with applicable standards, and validate sampling inspection (e.g., sampling conditions) except for 100% inspection.

## 16. Corrective and Preventive Actions

### (1) Corrective Action

A corrective action is required not only to handle nonconforming products and prevent the recurrence of nonconformities but also to remove the causes without delay. In addition, since a corrective action responds to the impact of the detected nonconformities, the manufacturer adopts various causal analysis methods in order to reliably identify the causes of the nonconformities.

To appropriately take a corrective action, the manufacturer documents a procedure that defines the following JIS Q 9001:2015 requirements.

a) reviewing nonconformities (including customer complaints, e.g., those from utilities)
b) determining the causes of nonconformities
c) evaluating the need for action to ensure that nonconformities do not recur
d) determining and implementing action needed
e) records of the results of the action taken (see “Control of Records”)
f) reviewing the effectiveness of the corrective action taken

In addition, the manufacturer takes into account the following matters and reflects them in the procedure.

- communicate the corrective action to the relevant divisions as necessary.
- extract quality assurance issues from nonconformity handing slips, nonconformity cases at preceding plants, etc., and take measures to prevent recurrence.
- report the measures to prevent the recurrence of nonconformities in accordance with an agreement with the utility.

### (2) Preventive Action

A preventive action is an action determined and taken for removing the causes of possible nonconformities in order to prevent such nonconformities from occurring. A preventive action must respond to the impact of a possible problem. Therefore, the manufacturer conducts causal analysis for nonconformities envisaged from knowledge, experience or information acquired through nonconformity control and corrective actions or for possible occurrence of similar nonconformities expected from various information of external origin and determines and takes preventive action according to the importance of the matter.

To appropriately implement preventive action, the manufacturer documents a procedure that defines the following JIS Q 9001:2015 requirements:

a) determining potential nonconformities and their cause,

b) evaluating the need for action to prevent occurrence of nonconformities,

c) determining and implementing action needed,

d) records of the results of the action taken (see “Control of Records”)

e) reviewing the effectiveness of the preventive action taken.

If necessary, the manufacturer reflects the preventive action in the procedure as a matter to be communicated to the nuclear-related divisions.